

Community Directed Treatment with Ivermectin

Report of a multi-country study



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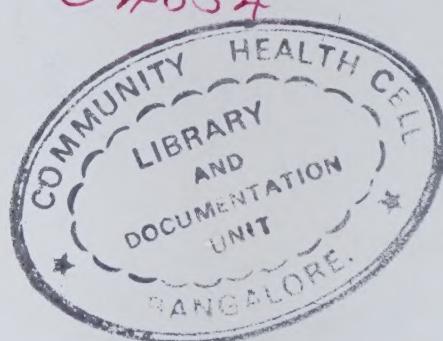
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(TDR)

in collaboration with the
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and the
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Community-Oriented Treatment
With Intervention

Report of a Multi-County Study

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CONTENTS

Introduction	3
Study Design and Methodology	5
Study objectives	5
Study design	6
Data analysis	11
Study Areas	13
Community Directed Treatment Approaches	19
Process	19
Structure	23
Changes in the system over time	33
Adherence to Appropriate Treatment Procedures	35
Exclusion criteria	35
Ivermectin dosage	39
Management of adverse reactions	43
Concluding remarks	45
Treatment Coverage	47
Overall treatment coverage	47
Treatment coverage by study design	49
Treatment coverage by study site	51
Factors related to Treatment Coverage	55
Comparison of communities with high, low and zero treatment coverage	55
Treatment coverage and characteristics of the distribution system	59
Multivariate analysis of factors related to treatment coverage	66
Concluding remarks	69
Reporting	71
Reported treatment coverage	71
Reported adverse reactions	74
Concluding remarks	74
Sustainability and Replicability	75
Sustainability indicators	75
Conclusions and Recommendations	79
Main conclusions	79
Recommendations	80

1. Introduction

Onchocerciasis remains a serious public health problem in large parts of tropical Africa where some 18 million people are affected. The most severe consequence of onchocerciasis is blindness, which may afflict over one third of the adult population of the most affected communities. Other important problems are severe skin disease and maddening itching which cause great suffering to millions of people.

The Onchocerciasis Control Programme in West Africa (OCP) has successfully controlled onchocerciasis as a public health problem throughout its area. However, its vector control operations, based on aerial larviciding, are not considered cost-effective for other endemic areas in Africa. Outside the OCP, therefore, there used to be virtually no onchocerciasis control. This changed in 1987 when ivermectin was registered for the treatment of human onchocerciasis. The subsequent availability, free of charge, of this safe and effective microfilaricide presented an opportunity to control the disease as a public health problem in all endemic areas in Africa.

To control onchocerciasis as a public health problem, ivermectin needs to be given at least once per year to the population of all seriously affected communities. Since ivermectin treatment has only limited effect on transmission of the parasite, annual large scale treatment will have to be continued for a very long time to ensure sustained control of the disease. The main challenge facing ivermectin-based control, therefore, is to develop and implement simple and effective methods of ivermectin delivery which are sustainable within the context of the socio-economic constraints of the endemic African countries.

A major breakthrough for onchocerciasis control was the creation in 1995 of the African Programme for Onchocerciasis Control (APOC) which covers the remaining 16 endemic African countries outside the OCP. The principal objective of APOC is "to establish, within a period of 12 years, effective and self-sustainable community-based ivermectin treatment throughout the remaining endemic areas in Africa".

Before the creation of APOC, community-based ivermectin treatment was already operational in several countries. The most advanced country was Mali where community-based delivery had been ongoing for several years in a several hundred communities. The results of these first community-based programmes appeared very positive and suggested that communities are capable and willing to take responsibility for their own ivermectin treatment. However, no systematic evaluation of these community-based programmes had been undertaken and most of the available information was anecdotal.

In order to provide objective scientific information on the effectiveness and sustainability of different approaches to community-based ivermectin treatment, the Task Force on Onchocerciasis Operational Research of the Special Programme for Research and Training in Tropical Diseases (TDR), in collaboration with the OCP, decided in 1994 to undertake a multi-country study on community-based treatment with ivermectin. This new initiative was advertised in the endemic African countries, and from the many applications received, the Task Force invited a selected group of investigators to a protocol development workshop which was held in June 1994 in Bamako.

The workshop participants, many of whom had considerable experience in ivermectin delivery, concluded that the study should go beyond a mere evaluation of ongoing treatment programmes and that it should experiment with different approaches to community-based treatment. In view of the need for sustainability, particular emphasis was to be given to the study of approaches in which the community is given a major responsibility for its own treatment. The participants introduced the term 'Community Self-treatment' to characterize such approaches; a term which was later changed to Community Directed Treatment (CDT).

On the basis of the standard protocol, the participating teams submitted research proposals to TDR and eight multi-disciplinary teams were selected to participate in the multi-country study. Six of the teams were funded by TDR and the other two by OCP.

Following a pilot study in all sites, the research protocol was reviewed and revised during a workshop in March 1995. The main study started in mid 1995 and was facilitated by a special donation of ivermectin from Merck & Co. All fieldwork was completed by May 1996. The preliminary results were presented by the investigators during a symposium held in June 1996 in Ouagadougou. Among the participants in the symposium were representatives from Ministries of Health, Non-Governmental Development Organizations, OCP (including the members of its Expert Advisory Committee), APOC and TDR. The final analysis, guided by the feedback from the symposium participants, was completed in September 1996. The main results of the study are presented in this report.

2. Study Design and Methodology

2.1. Study objectives

General Objective

To identify and develop simple, acceptable and sustainable methods for Community Directed Treatment with ivermectin.

Specific objectives

To investigate two different approaches to Community Directed Treatment for onchocerciasis as described below.

- Programme-designed (PD): methods which were developed in collaboration with onchocerciasis control programmes and were then proposed to the community.
- Community designed (CD): methods which were identified by the community itself.

The two methods were assessed and evaluated using the following broad criteria:

- Drug delivery:
 - process,
 - structure
 - changes in the method over time
- Procurement of ivermectin
- Adherence to appropriate treatment protocols:
 - exclusion criteria,
 - dosage
 - referral of severe adverse reactions
- Effectiveness of supervisory strategies
- Treatment coverage achieved
- Factors related to treatment coverage
- Reporting

The study also aimed to identify and describe:

- factors of relevance to the sustainability of the different delivery systems, including treatment procedures, motivating factors and community involvement.
- factors of relevance to the replicability of the methods in other endemic communities in Africa.

2.2. Study design

The study compared the feasibility and acceptability of Programme Designed and Community Designed approaches to Community Directed Treatment with ivermectin.

2.2.1 METHODS OF COMMUNITY DIRECTED TREATMENT

a Programme Designed

In this method of Community Directed Treatment, the criteria for the selection of Community Directed Distributors and the procedures followed were pre-designed by the control programme staff on the basis of their experience and their best judgement on how the treatment should be organized. The communities would then be requested to develop their Community Directed Treatment system in accordance with these criteria.

b Community Designed

In this method there was no pre-conceived design. The only component of the method which was designed was the health education/information session with the community when it was provided with explicit information on onchocerciasis, the effectiveness of ivermectin, the need for annual treatment of all eligible members of the community, and the required treatment procedures such as height measurement to determine the dosage. The community then was invited to design a method for delivery of the drug by the community itself. This proposed method was then be implemented in the study.

2.2.2 STUDY POPULATIONS

The study unit was the community or village. Study villages were preferably hyper-endemic, or at least meso-endemic villages where large scale ivermectin treatment is indicated. Study villages had a population of between 200 and 1000 people.

The number of study villages per team depended on the number of control programme-designed delivery methods. In the simplest case of only one control programme-designed method, there was at least 20 villages selected for this method, and an equal number of villages for the community-designed method, bringing the total number of study villages to at least 40 villages.

2.2.3 HEALTH EDUCATION

Health education (HE) and community mobilization was pursued as an integral part of both the control program and community design approaches to ivermectin self treatment. Health education activities were geared towards the assurance of a two way feed back with regards to knowledge, awareness, perception and observable attitudinal changes about onchocerciasis and its treatment.

Appropriate health education messages in the form of posters, pamphlets and verbal presentations were therefore developed and tested to address the following issues:

ISSUES	Health Education Messages
Knowledge of the disease	<ul style="list-style-type: none"> . Local name of the disease . Symptoms . Causation . Transmission
Knowledge of treatment	<ul style="list-style-type: none"> . Previous experiences (e.g. DEC, Local treatment) . Introduce ivermectin (Mectizan®) <ul style="list-style-type: none"> . Dosage . Exclusions . Reactions . Beneficial side effects
Attitude to treatment	<ul style="list-style-type: none"> . Advantages of treatment Free Yearly treatment Possibility of self treatment at community level Importance of maximal coverage
Attitude to disease	<ul style="list-style-type: none"> . The disease can be controlled . Onchocerciasis blindness and skin changes can be prevented
Attitude to the distributor	<ul style="list-style-type: none"> . The community chooses the distributor(s) . age . trust . sex (gender) . literacy level/ability for record keeping
Attitude to good record keeping and information/ record sharing	<ul style="list-style-type: none"> . Minimum requirements for record keeping . records are confidential and strictly for health issues . Records required are for subsequent drug supply

The possibility of using the media (particularly the radio) and ancillary aids was also to be considered.

The development of the required health education messages was achieved utilizing a pre-treatment KAP survey and the messages were tested during the pilot study.

2.2.4 TRAINING OF COMMUNITY DIRECTED DISTRIBUTORS (CDDs)

Each team decided on where and when to organize the training of ivermectin distributors. The curriculum focussed on the disease (definition, transmission, clinical manifestations and treatment) and the control program. At the end of the training, the ivermectin distributors should have been able to:

1. Describe the major clinical manifestations
2. Describe the different methods of treatment (central point vs house to house)
3. Have a good knowledge of and effectively carry out the following ivermectin distribution related activities:
 - Community mobilization
 - Household enumeration

- Guidelines on the period and the duration of treatment
- Guidelines for the exclusion criteria
- Correct dosage using height
- Reassure for minor adverse reactions and refer severe adverse reactions
- Record keeping on:
 - number of people treated
 - number of defaulters
 - number of tablets lost
 - number of tablets used
 - number of tablets returned
 - severe adverse reactions
- Training other fellow villagers
- When and where to collect ivermectin tablets
- Benefits and the side effects of the drug

The ivermectin distributors should have been able to identify and report on the difficulties/problems encountered during the distribution.

The training lasted a maximum of three days and consisted of theoretical sessions and practical field exercises. During the pilot study, the evaluation of the training was carried out to ensure that the ivermectin distributors mastered the skills they were taught.

The training requirements for the Community Design villages were determined after the community had decided on its strategy for the distribution of ivermectin. The training guidelines as outlined above were modified for the specific community designed approach.

2.2.5 TREATMENT OF THE ELIGIBLE POPULATION

Dosage Determination

Dosage was determined using height measurements (according to the protocol of Merck & Co. Inc.). A vertical wall in an appropriate place in the village or a stick was calibrated to serve as the measuring instrument. Four dosage treatments which were indicated on the instrument, were to be adhered to based on the results of the measurements as follow.

Height (cm)	Dosage (tablets)
90 - 119	½
120 - 140	1
141 - 158	1½
159 or more	2

Tablets were to be swallowed in the presence of the distributor. Defaulters as well as those who did not receive tablets on account of exclusion criteria should also swallow tablets in the presence of distributors when subsequently they became available or eligible to take treatment.

Exclusion Criteria

Certain individuals in the population may not be eligible for treatment at the regular scheduled time of ivermectin distribution. They were identified through the exclusion criteria which are:

1. Children under 5 years of age or inability to touch the opposite ear or height below 90 cm.
2. Pregnancy, which can be determined through observation or questioning.
3. Seriously ill individuals.
4. Lactating mothers during the first week of lactation.

Treatment Cycle (Duration of Distribution)

A maximum of 3 months were allowed for regular treatment as well as treatment of defaulters. All unused tablets were to be returned to the central store or the supervisor.

Monitoring of Adverse Reactions

Monitoring was to be undertaken by ivermectin distributors. Those with minor reactions were to be reassured only. Those with severe reactions were to be advised to report to the nearest health centre. The distributor was however required to record (and report) severe reactions by describing them.

2.2.6 SUPERVISION AND REPORTING

Two types of supervision were used: no supervision during the study period and minimal supervision. The two approaches to supervision were used in 50% of each of the study communities in both the programme -designed and community designed sites.

a No supervision

After the initial approach and training of the community, there was no further contact with either the researchers or government health officials and the communities until the end of the study - with the exception of the collection or drop-off of ivermectin.

b Minimal supervision

This was by government health officials at the level closest to the communities e.g.

Nigeria: LGA onchocerciasis coordinator

Ghana: Level B supervisor

Uganda: assistant field officer etc.

The supervisor contacted the community on two occasions:

- a) during the initial contact with the community (including training) and
- b) shortly after an agreed upon period of distribution to review
 - record keeping
 - ivermectin inventory
 - adherence to exclusion criteria
 - dosage

2.2.7 REPORTING

Standardized data were to be collected from all communities as follows;

- period of treatment
- total population (of village)
- total number of people treated
- severe adverse reactions, specifically difficulty in breathing, dizziness/difficulties in walking
- number of tablets received
- number of tablets distributed
- number of tablets kept for absentees, pregnant women and sick people
- number of tablets to be returned
- number of tablets required for next distribution cycle

In community designed programmes the design of the record keeping was left to the community. In the programme design communities there were two options:

- notebook + summary form + severe adverse reaction form or
- the simplified pictorial forms

2.2.8 EVALUATION

Qualitative and Quantitative methods were used for evaluation. The first round of data collection for evaluation was planned to be carried out in a subsample of villages as follows;

- 2 program-designed villages with no supervision
- 2 program designed villages with minimal supervision
- 4 community designed villages with no supervision
- 4 community designed villages with minimal supervision

Qualitative information was collected through in-depth interviews and focus group discussions which began about 2 months after the agreed starting date of distribution.

a Final evaluation

Information from the analysis of the data of the first evaluation was used in a workshop in Accra, January 1996, to finalize the evaluation instruments and plan the final round of data collection. The final evaluation was carried out in the remaining villages between 4 and 8 weeks after the second round of treatment. The forms and procedures were modified during the workshop and the final round involved the following procedures:

- a) Household surveys. A sample of households in each community were interviewed using a structured interview; a household being defined as a group of people who normally eat together.
- b) Observation notes (OBS). The ivermectin distribution system was described in the village observation notes which were based on the information obtained in the initial and subsequent visits to the villages.

c) in-depth interviews (INDEPTH or IDP)

These were conducted at each collaborating site in all remaining villages of both types of programme design. Two in-depth interviews were held in each of the villages, one with the village leader (IDL) and the other with the distributor or person responsible for the ivermectin distribution (IDD).

c) focus group discussions. (FGD)

These were conducted with adult women in all villages and with men in 2 villages per site. Permission of the village chief and consent from adults was obtained for the selection of participants who were representative of the village population thus were not leaders, health workers or other notably prominent persons.

2.3. Data analysis

The quantitative data collected during the household survey and the information on the treatment reporting form were entered in the computer using standard data entry programmes developed in EPI-INFO 6 and used by all study sites. Analysis for the quantitative data was done using SPSS 7.0 for Windows.

The qualitative data from the observation notes, focus group discussions and in-depth interviews were entered using WordPerfect, and were subsequently coded for analysis using TEXT-BASE ALPHA. For each village, a summary record was created which contained information from the qualitative data on key variables. The information in the key variables was coded and linked an SPSS data base which contained per community the aggregate quantitative data from the household survey and the reporting form.

In the presentation of the results in this report, use is made of so-called box-plots to describe the distribution of treatment coverage in relation to different variables. As many readers may not be familiar with these type of graphs, a guide to their interpretation is given below:

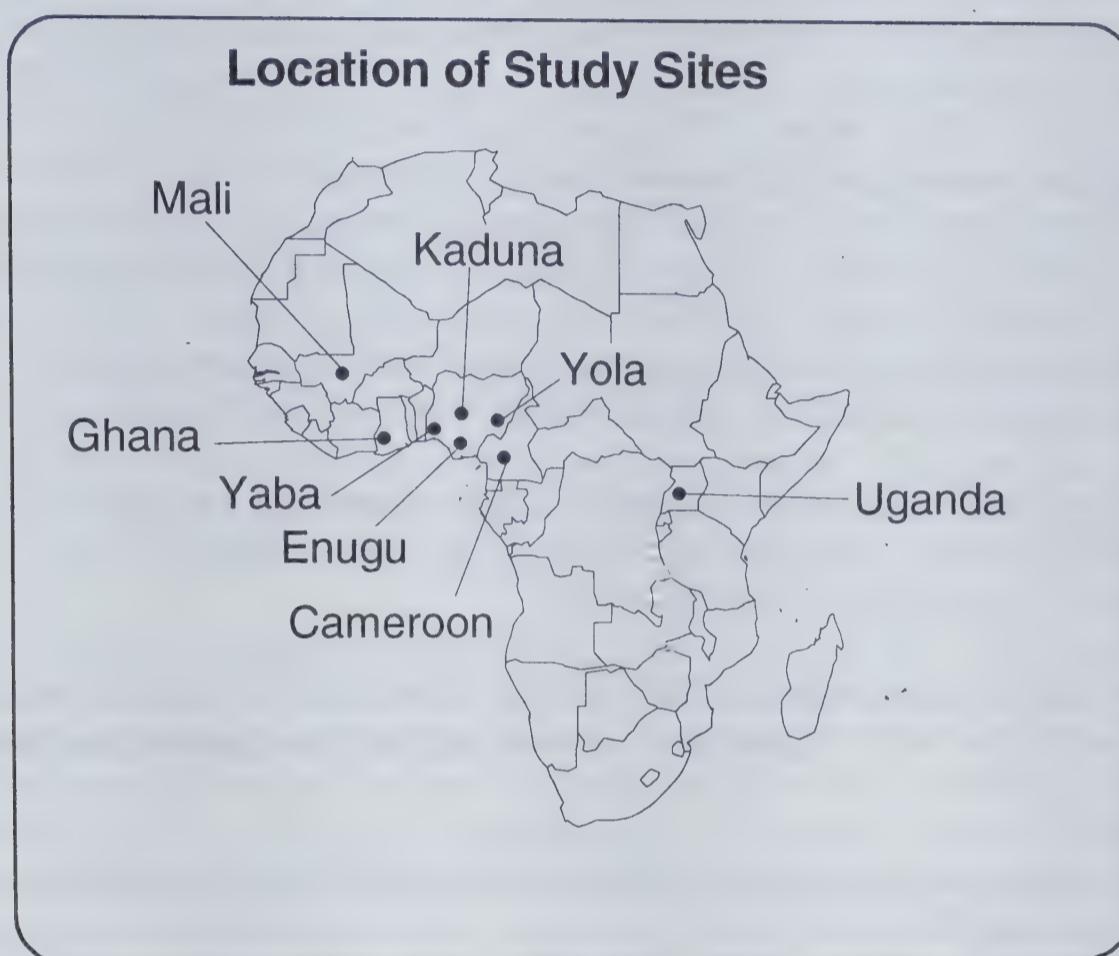
Guide to the interpretation of box-plots

Symbol	Meaning
	Largest value
	75th percentile
	Median
	25th percentile
	Smallest value that isn't an outlier
	Outliers: Values more than 1.5 box-lengths below 25th percentile
	Extreme: Value more than 3 box-lengths below 25th percentile



3. Study Areas

The study was carried out in eight study sites in Africa (see map below). Four of these sites were in Nigeria, i.e. Enugu, Kaduna, Yaba and Yola. The other sites were in Cameroon, Ghana, Mali and Uganda. Ghana and Mali are countries in the OCP, and all other sites are in APOC countries.



3.1. Cameroon

The study was carried out in the Bangante health district, Western Province of Cameroon. Geographically, it is highland country with numerous hills and deep valleys with many fast running streams and rivers. The classical tropical savannah distribution pattern is a common feature.

Many ethnic groups exist but the prominent one is the Bamileke, who are basically traders and subsistence agricultural farmers. Reports indicate that onchocerciasis is endemic in the region, and has a focal distribution along the main river systems. It is meso endemic for onchocerciasis. Ten Health areas in the Bangangte Health District were chosen for study.

A special characteristic of the Cameroon study site is the existence of a cost recovery system. The current cost-recovery mechanism with relation to ivermectin delivery is a charge of CFA 100 per person per treatment. This cost recovery system was incorporated in half of the study villages (both in PD and CD) but it was not applied in the other 50% of the study villages.

3.2. Enugu

The study in Enugu site was carried out in Nike community in Enugu North Local Government Area and Etteh Community in Egboeze North Local Government Area. Both communities are in Enugu State in South Eastern Nigeria but are about 65 km apart. Enugu State is located in the Forest-Savannah transitional mosaic zone of Nigeria and shares common boundaries with Benue State in the North, Anambra State to the Southwest, Cross River State to the Southeast and Imo State to the South.

The estimated population of both study areas is about 30,000. While Etteh population is a bit dispersed, Nike is compact but both populations are stable. The inhabitants are predominantly Igbos with a few Igalias in Etteh community. Their religion is mainly Christianity in Nike and in Etteh with about 30% Moslems in Etteh as well. The main occupation in both communities is subsistence farming. Each of the communities is traversed by a major river, Iyiocha in Nike and Ubele in Etteh, around which farming activities go on and these are well-known breeding sites for Simulium flies. The leadership system is democratic. The people elect their traditional ruler and he administers the affairs of the community with the councillors and elders. There are both male and female, socio-cultural groups in the communities. Literacy level is high. The villages are connected to each other by untarred but motorable roads some of which become inaccessible during the rainy season.

There is generally a lack of basic amenities. Etteh community has only one Health Centre serving the whole community while Nike has only two. The source of drinking water is mainly from wells and streams. Electricity Supply is still sparse.

Onchocerciasis is hyper endemic in the two areas according to the report of the application of the Rapid Assessment Method of diagnosing the disease and also from parasitological surveys carried out here in previous studies. None of the communities have had ivermectin treatment before.

Nike community was designated the Programme design (PD) area while Etteh was designated the Community design (CD) area.

3.3. Ghana

The study was undertaken in Ashanti, Eastern and the Central regions of the country. There was a district each from Eastern and Central regions and 2 from Ashanti. These districts lie in the tropical rain forest belt of West Africa with 2 rainy seasons. There are 2 main rivers, Pra and Birim draining this area with a lot of tributaries. These two rivers flow all year round with all the numerous tributaries over flowing during the rainy season. Thus conditions are favourable for the breeding of the blackfly.

The main ethnic group in the area is the Akan. There are pockets of migrant groups from other tribes mainly the Ewes. The main occupation is farming and food processing. They are Christians. The total population of the study area is 600 000. Functional literacy is about 30%.

Health facilities are generally accessible; the average distance is about 15 km from most villages. Schools are available in most villages. Villages are accessible through untarred roads. However, accessibility is impaired during the rainy season when the roads become bad. Potable water is currently being provided for most villages through the provision of boreholes.

The prevalence of Onchocerciasis is between 20% to 50% by nodule assessment. The main manifestation of onchocerciasis is skin disease.

3.4. Kaduna

The study for the Kaduna site was carried out in Ofu and Idah Local Government Areas (LGAs) of Kogi State, Nigeria. Kogi State is in the middle belt of Nigeria and has forest-mosaic vegetation, with several mountainous areas. The State shares boundaries with Enugu State (South East), Benue State (North), Kwara State (West), Edo State (South West), Benue State (East) and the Federal Capital Territory - (FCT) in the North.

The inhabitants of the study areas are Igalias and with some mixed communities of Igbos. The main language is Igala, with some Igbo speaking communities. Apart from the few satellite towns in Igala land, the majority of them settle in rural villages.

Onchocerciasis is hyper endemic in most communities in the two LGAs as determined with the Rapid Assessment Method (RAM) using nodules and leopard skin as indicators and skin snip surveys. All the study villages have high prevalence levels of onchocerciasis and had no previous experience with ivermectin. However, members of several communities have had previous experiences with Banocide treatment

The population of the communities studied varied between 200 and 1200. The major river systems in the areas are tributaries of River Inachalo, R. Ofu and R. Anambra. Most of the rivers and streams in the areas are fast flowing with breeding sites for blackflies.

The inhabitants of the forty villages are predominantly subsistence farmers and the major crops cultivated include cassava, beans, groundnuts and yams. Palm oil is produced in large scale because of the abundant natural palm trees in the areas. Women process and market the various farm produce including palm oil.

The leadership system in the area is hierarchical and almost always hereditary. Each village is governed by a village head called "Madaki". A group of villages (2 - 4) are under a senior village head referred to as "Gago" who are responsible to the district head known as "Onu", while all the Onus are under the paramount chief of the Local Government called "Eje". There are several socio - cultural groups for women, men and youths.

Most of the communities are at the end of the road. Socio-economic profiles of the villages show lack of basic amenities such as good roads, electricity, pipe borne or bore hole water. During the rains, most of the communities are inaccessible because of the poor roads. The villages are served by few health centres and primary schools, and the literacy level is very low.

3.5. Mali

The study sites in Mali were, Kita, Banguineda and Bougouni, located in the three regions of Kayes, Koulikoro and Sikasso respectively. Kita was the first area to have a community self treatment programme while the other two have community-based treatment organized by the National Programme of Onchocerciasis Control and Non-Governmental Organizations.

Kita is situated in the west of Mali. It has a typical Guinean habitat characterized by a relatively high rainfall and dense network of water courses. Farming is the main economic activity. The majority of the population is Malinke, with some Peuls and Bambara, and Christians, Moslems and people of traditional beliefs are represented.

The population is over 30,000, most of whom have no access to health facilities. In spite of efforts at improving literacy, illiteracy is still over 90% It is an area with much economic potential which is a focus of several development programmes.

Banguineda, in spite of its proximity to Bamako has weak health infrastructure. The population is mainly Bambara with more than 26,000 inhabitants, whose principal occupation is agriculture. Literacy is higher here than in Kita. It has Guinean -savanna habitat with relatively high rainfall. It is also meso-endemic for onchocerciasis.

Bougouni, the third study site, has the same economic potential like Kita. The majority of the population are Peul, followed by Malinke and Bambara. Islam is the main religion. Christianity and traditional beliefs are less important. There are some 30,000 inhabitants. The level of illiteracy is very high as in other rural areas of Mali. Most of the villages do not have health facilities.

The study sites have similar socio-economic profiles. These areas were hyper endemic for onchocerciasis before the intervention from OCP. Ivermectin was introduced into the strategy of onchocerciasis control in these areas in 1992 especially in the areas of Baguineda and Bougouni where community-based treatment was first started in Mali. Kita did not receive ivermectin treatment until the end of 1995 when the Community Directed Treatment study was started.

3.6. Uganda

The study was carried out in North-Western Uganda in Arua district. The district is approximately 500 miles from Kampala, the Capital City. The area is fairly fertile and people grow many food crops and tobacco as a cash crop. The rains are bimodal with the longer rains coming between April to early July and the shorter one coming between August and September. The topography is one of undulating hills and there are many locally made bridges over the numerous seasonal and permanent streams that criss-cross the valleys in the district. The vegetation is mainly Savanna woodland type. In spite of the fertility of the area it is sparsely populated but permanently settled and in clusters. The population of the district is over 300,000 people. Arua district is highly endemic for onchocerciasis with some villages having a nodule prevalence close to 100%. The district borders Sudan in the North and Zaire in the West and more than 100,000 Sudanese refugees many of whom are thought to be infected with the blinding strain of *Onchocerca volvulus*, have settled in the area.

Two subcounties namely Offaka and Vurra were selected for the two approaches of Community Directed Treatment and are 67 miles apart. The Community Designed (CD) approach was implemented in Vurra subcounty and the Programme Designed (PD) in Offaka subcounty. In all, 40 villages were selected for the study. Twenty four were selected for the CD approach and 16 for the PD. During the first evaluation, which was mainly qualitative, 8 villages were sampled for data collection from the CD area and 4 villages in the PD area.

Following the Study Protocol, the Ugandan research team contacted the district officials and informed them about the study and got their cooperation. Thereafter they proceeded to the villages and mobilised people through their leaders and told them about the needs to be done. In the CD areas the

leaders and community members gathered were told to design their own treatment procedure in terms of persons involved and resources required.

3.7. Yaba

The study was carried out in Iwo and Aiyedire Local Government Areas (LGAs) of Osun State, Nigeria. Osun State lies in the forest area in the South Western part of Nigeria, and formed part of old Oyo State up to 1991, when it was created. The study area has a population of 268,000 predominantly made up of the Yoruba ethnic group. The people are mainly Muslim and there is a high level of illiteracy in the area. The LGAs are mostly made up of villages, the two main towns of Iwo and Aiyedire where the Local Government headquarters are located and a few other towns. Only these main towns enjoy electricity and pipe-borne water. The villages and other towns lack these basic facilities which compel the people to resort to the nearby rivers and streams for their needs, thereby further exposing them to *Simulium* bites.

River Osun, which is the main river, and many smaller rivers and streams flow close by the settlements and farmlands. These are all fast flowing, particularly in the rainy season, providing favourable habitats for *Simulium* breeding.

Onchocerciasis is hyper endemic in the communities studied according to the 1994 REMO data for the State. None of the communities had previous experience with ivermectin. The population size of the villages varied between 200 and 1120.

"Village areas" are a feature in the geographical set up in the study area. A village area consists of the main (larger) village and other satellite villages or hamlets, over which it has control. The Baale (village chief) heads the village and is, in most cases assisted by the Bale (a lower chief) and some other village elders. Some of the villages are end of the road villages and become inaccessible during the rainy season when the approach roads become washed away. Most of the villages also do not have a dispensary which is the basic health unit although there is a health policy that a basic health post should be within 5 km radius of every community. Primary schools do not exist in every village, but are available in nearby villages.

The main occupations are subsistence farming and hunting. Palm oil processing is a feature of the area, the manpower for which is largely made up of women. Some of the crops farmed are yams, melon, oranges, plantain, cassava, bananas.

There is a weekly surge of villagers to the two main towns of Iwo and Aiyedire on Fridays for prayers, and also on every weekly market days. Indeed most villagers, on attending the Friday mosque prayers end up spending their week end there. This practice is also evident during the annual "Egungun" fetish festival which many a time results in empty villages for those villages involved. The villagers also have residences or family quarters in these towns and look upon these also as homes; as there very strong family ties between the villages and the towns.

3.8. Yola

The Yola team carried out the study in Takum Local Government Area, a guinea savanna area of northeastern Nigeria. The area is very mountainous with numerous rivers which provide extensive blackfly breeding sites throughout the year.

The estimated population of the area is 170,000 inhabiting about 88 villages most of which are located at the foot of the hills. The main ethnic groups are Kuteb, Jukun and Ichen who despite differences in ethnic origins have similar cultural norm and values. Christian and Islamic traditional religions are predominant. The major occupations of the people are farming and cattle rearing especially along the river valleys.

The social organization of each community is lineage-based with the village head at the apex while family heads constitute the village council. General administration and decision-making are the responsibility of the village head and his council. While women constitute a significant proportion of the village population, they do not directly participate in decision-making although they attend village gatherings.

A group of villages with a close ethnic and historical affinity constitute a traditional district, at the apex of which is a District head. Our study area is made up of three such districts namely, Takum, Manya and Kashimbila. Each District Head has an office and staff. This traditional administrative structure is typical of northeastern Nigeria and is accorded constitutional recognition. Although the illiteracy rate is generally high, it is possible to find at least one literate person in every village. Generally the roads leading to most of the villages are un-motorable and communities are often cut off during the rainy season.

The entire area is categorised as hyper endemic for onchocerciasis. The presence of numerous vector breeding sites, the main occupation of the people and the lack of development of the area explain the high level of endemicity. There is no systematic intervention programme in the area. However the Catholic church carries out focal clinic-based treatment in a few villages.

4. Community Directed Treatment Approaches

In a Community Directed Treatment system, the community itself is in charge of the execution of the system, including the treatment of all eligible members of the community, collection of the drug, referral of severe adverse reactions and reporting. Community Directed Treatment systems vary with respect to process and structure, including the characteristics of distributors, mode of drug procurement, mode of distribution, cost sharing and level of supervision. This chapter describes the wide range of Community Directed Treatment systems encountered during the study, starting with overview of the process, followed by description of the various structures and ending with a summary of changes made in the system by the communities during the study period.

4.1. Process

The process leading to decisions on the modalities for the distribution of ivermectin differed between the Programme-designed and the Community-designed approaches. There were also differences between and within sites. The key components of the process were: the approach to the community; health education and information provided; the decision making process which involved the selection of distributors; the mode of distribution of ivermectin, and changes to the system.

4.1.1 APPROACH TO THE COMMUNITY

Across sites, the common mode of establishing first contact with the communities took cognisance of the already established chain of communication of the Ministry of Health of each participating country. In this regard, a research team first informed the regional/state directors of health about the proposed study, its objectives, the areas to be covered and the proposed date of commencement of the study. Next, the team visited the district/local health managers to acquaint them with the study and to solicit their support especially in identifying and establishing contact with the selected communities. The mode of handling the tablets was also discussed. With the help of these district/local officers, local contact persons - often the village chief and (or) his elders - were initially contacted.

During the first contact, the village chief or his representative was briefed on the purpose and rationale of the study. The research team then requested to meet the entire community on a mutually agreeable and agreed day. This often coincided with the village's day of rest when the vast majority of residents were most likely to be around in the village. This first contact was usually quite brief. The chief or his representative often asked to be given time to consult with the elders. Thus on the average the initial approach to the community consisted of two visits by the research teams.

At the second visit, on the appointed day, and at the village gathering, the team discussed with the chief, his elders and members of the community of both sexes, issues relating to the burden of onchocerciasis, mode of transmission of infection and the benefits to be derived from its elimination. This over, the team then explained the nature of the study and introduced the onchocerciasis control package which centred on treatment with ivermectin. The role of the community as envisaged in the

study design for the particular community was also explained to the village gathering. Each meeting was usually ended with the question and answer session. Villagers asked questions on issues that were not clear to them and answers were provided as truthfully as possible.

4.1.2 HEALTH INFORMATION/EDUCATION

Health education and basic information about the use of ivermectin was provided to the entire community. The following subjects were dealt with by all teams:

- . when and where to collect the tablets
- . people eligible for taking the tablets
- . people excluded from taking the tablets
- . how often the tablets should be taken
- . how individual dose is determined
- . how the tablets are taken
- . possible side effects and their management

Subsequently, once distributors have been selected, these subjects were not only discussed (with distributors), in greater and more precise details but additional information was also given on how to account for the tablets using the various reporting forms designed for the study. At the end of the health education sessions, participants were given the opportunity to ask questions. This enabled the teams to assess the adequacy of the health education.

In all communities, health education ended with the selection of distributors. In the CD sites, communities were given the freedom to select their own distributors and mode of distribution while in the PD sites, the mode of distribution as well as the process of selection of distributors were made to conform to the criteria on distributor characteristics which had been pre-determined in accordance with the study design put up by the research team.

The following quotations are a sample that illustrate the health education approaches as reported from various sites:

"A series of village meetings were held after which registration, health education, training, venue selection, and final drug administration (procedure) were discussed" (MALI)

"The doctors told us something about the drugs; those who should take the tablets and those who should not; and also that height was important" (YOLA)

"Health educators first told people why they are taking the tablets and as they went round from house to house, they also emphasised it (UGANDA)

"The team from Accra gave us health education on onchocerciasis. and ivermectin. They educated us that people who were ill and those who had taken alcohol that moment were not to take the drug until sometime later" (GHANA)

"The villagers were made to know that ivermectin prevents and cures river blindness. Those who are ineligible were to be excluded through serious warnings" (ENUGU)

4.1.3 DECISION MAKING PROCESS

There was a wide range and variety in the manner by which decisions were made in the different communities with respect to selection of distributors, mode of distribution to be used, conduct of census, when and how ivermectin tablets were to be collected from a designated central point, and any subsequent change in the system.

In discussing and taking decision on the above issues, the series of meetings involved the participation of one or more of the following people and groups: village head, council of elders or chiefs, local government official resident in the communities, social and health committee members, health workers, religions leaders, and various segments of the community. Three major classifications of the decision making process were obtained: decision by leader, some participation and much participation. The term decision by leader is used to describe a decision making process in which only the village head/leaders and their council of chiefs were involved. When some village committee members were involved in the decision in addition to the village head and chiefs, the process is described as some participation. The process of reaching decisions during village assemblies is classified as much participation.

The following quotations exemplify the different configurations listed above:

Village leader's decision

"The Madaki selected them (the distributors) because he wanted them to represent the community. We agreed unanimously with the selection" (FG, KADUNA)

"He was appointed by the village head; we all supported it..we all approved it. We are satisfied with whoever he selected" (FG, YABA)

"The village head, with his advisers chose us and they announced it publicly at a meeting" (INDEPTH, YABA).

"Their respective hamlet leaders selected them for the distribution" (FG, KADUNA)

It should be noted that the villages in which some decisions about the distribution system were taken outside of the community were included in this category. Half of the villages with the programme designed distribution system in the Mali site fell into this category. The NGDO which had been active in the distribution of ivermectin in the study sites that fell within its area of operation took all relevant decisions relating to drug procurement and distribution on behalf of the PD communities concerned.

Village committee decision (Some participation)

"The village health committee met with the village head. Decision on the method of distribution and selection of distributors was taken in the meeting" (OBS, CAMEROON)

Village assembly decision (Much participation)

"All the people representing different clans 'Umuna' in the village were in attendance" (INDEPTH, ENUGU)

"... method was arrived at in the village assembly involving women and men's representatives" (INDEPTH, GHANA)

"The elders and the local officials as well as the CDDs and the community all participated in developing the programme from the beginning to the end." (MALI)

a Decision making in PD

Each team designed the basic modality for drug distribution in the PD communities and proposed it to the community. Decision making by the community was limited to some aspects of the programme which varied across sites. These included: the selection of distributors but according to criteria specified by the research team; how the census should be conducted; when and how to collect the drug from a central point; and the location within the community where, in the case of the central mode of distribution, the distribution of ivermectin should take place.

Across sites the decision making process revolved around the village head and his council of chiefs (cabinet) and village elders. The degree of participation of individuals and groups varied from site to site. The involvement of women in the decision making process was negligible to non-existent in most sites.

b Decision making in CD

In CD, all aspects of the modality for the execution of the programme were decided upon by the communities themselves. The process had no pre-conceived design by the research team. The team only provided information which was meant to guide the communities in developing suitable strategies for community directed ivermectin treatment. The teams acted only as facilitators.

At some sites decisions were difficult to make at the first couple of meetings, and other meetings had to be planned. Participation in the subsequent meetings was usually enlarged.

A broad spectrum of individuals took part in the decision making process in Cameroon. This included the paramount chief, sub-chiefs, notables and council of elders.

"The method was arrived at in the village chiefs compound. Participants were chief of health centre, quarter heads and village health committee representatives. Two distributors were selected".(CAMEROON, VILLAGE SUMMARY)

In Ghana, chiefs, elders, cocoa buying societies and health development committees featured prominently in the process of designing the programme for ivermectin distribution.

In one instance, "The whole village met and selected the chairman and secretary of the village committee. The secretary had worked in a hospital" (GHANA, IN-DEPTH).

In Kaduna, the decision making process revolved around the paramount chief, village leader, council of elders, village assembly, development and health committees.

Village elders took most of the decisions in the Enugu and Mali study sites.

Decision making process in the Yaba study sites revolved around the village head and his chiefs. Some decisions were also taken in the village meeting.

In Yola, village heads, elders and opinion leaders participated actively in the process of making decisions about the programme.

In Uganda, the decision making process revolved around Elders, local council officers resident in the villages, religious leaders and parish chiefs. Religious leaders played crucial roles in the process of designing mode of distribution and the selection of distributors.

"The elders and the local officials as well as the distributors worked collectively at every stage in the planning, registering, drug collection, mobilization and determination of venue". (Male FGD UGANDA)

Participation of women was low or not reported at all in most of the sites. In some sites, Cameroon, Kaduna, Enugu, Ghana and Yaba, women attended meetings but did not contribute much towards making any decision. In the planning stages participation of women was generally limited. However, women were chosen as distributors in some of the villages. The limited participation of women in decision making processes is reflected by the following statement from Cameroon:

"We (females) were present in the general assembly meeting called by our leader but were asked to sit at the back, and only a few of us had anything to say". (CAMEROON, Female FGD)

"The distributors were selected in front of the community members. Although women were present at the meeting, they were nor apart of the decision making" (KADUNA, OBS)

4.2. Structure

There were six key components to the structure of the CDT approach. These were: The characteristics of the distributors; the mode of distribution of the drug; the method of procurement and collection of the drug from a central collecting point; the channel of communication within the community; the mode of treatment or dispensing the drug, the referral of adverse reactions and supervision. There were more variations in the structure in the CD than in the PD approaches, mainly because most of the elements of the structure were pre-determined by the research team in respect of PD while virtually all the structures were put in place by the communities themselves in the case of CD.

4.2.1 SELECTION AND CHARACTERISTICS OF DISTRIBUTORS

Different teams and communities had different and varying criteria for the selection of those to distribute the drug in the community. Some basic social and demographic characteristics featured prominently. Among these were social status (village head, civil servants), place of birth, education, sex and training. Also of considerable importance across sites were attributes like honesty and integrity as well as trustworthiness, diligence, competence and amiable disposition. Some or a combination of these criteria were used in different communities. The number of these community-directed distributors (CDD) selected also varied from one community to the other.

a Programme-Designed

In PD the process of selection of CDDs was essentially a two-step affair. First, the research team defined the basic characteristics expected of a CDD.

Head nurses were to be selected as distributors in the Cameroon while in Yaba, Kaduna and Mali literacy was a prerequisite. In Yola the distributors to be selected had to be females in half the villages and village heads in the other half. For a person to qualify as distributor in Ghana, he/she had to be a head of household (family head). In Uganda the village was to select as many as 9 distributors.

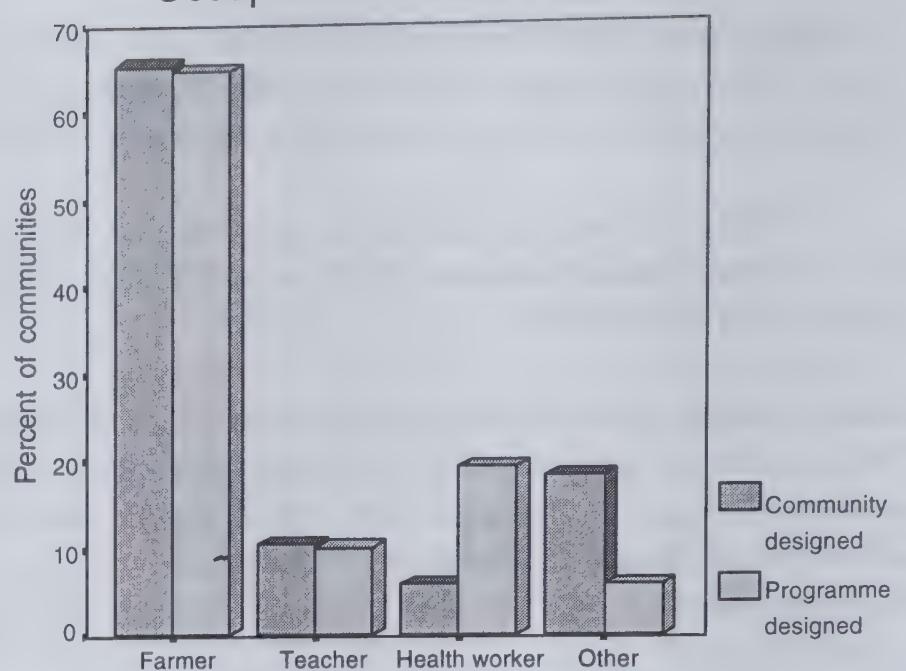
The next step was the actual selection of distributors. This was based on the prescribed characteristics of the CDDs, where such had been defined, within the frame work of the decision making process that existed in the communities.

In Mali, both the characteristics and selection of CDDs were initiated in 50% of the PD communities by the NGDO operating in the study area. Young men who were natives of the community and literate in French or in the local language, (Bambara), were selected as distributors. All were male and farmers. Literacy was a criterion dictated by the programme design.

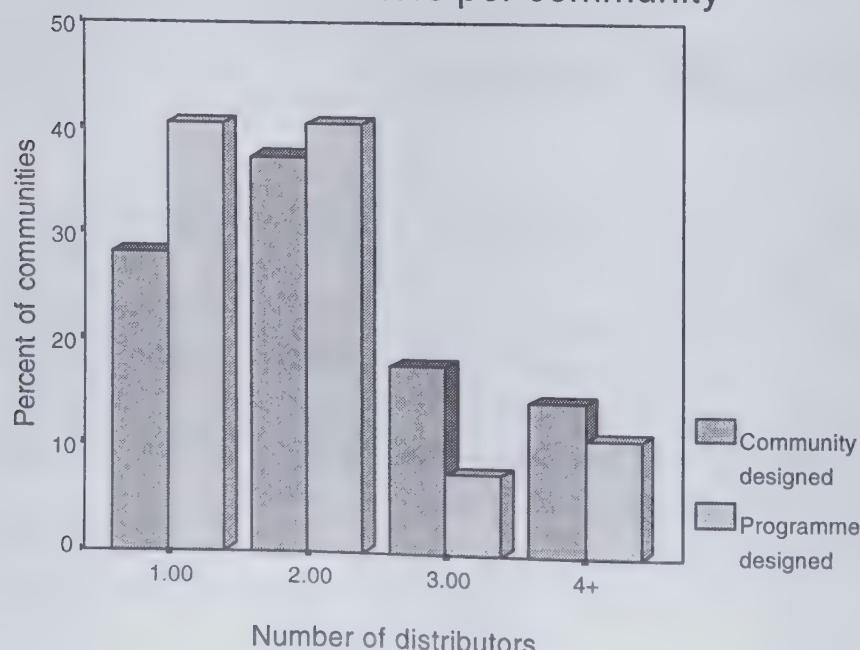
In Yaba the criteria used were competence, high level of commitment, and literacy. The selected CDDs were all farmers and indigenes who were normally resident in the village.

In Enugu the commonest criteria for selecting the distributor were being an indigene of the village and being educated.

Occupation of distributors



Number of distributors per community



" The distributors are from our village. Distributors are school leavers" (Enugu).

Male distributors were preferred and in some communities civil servants or health workers were selected.

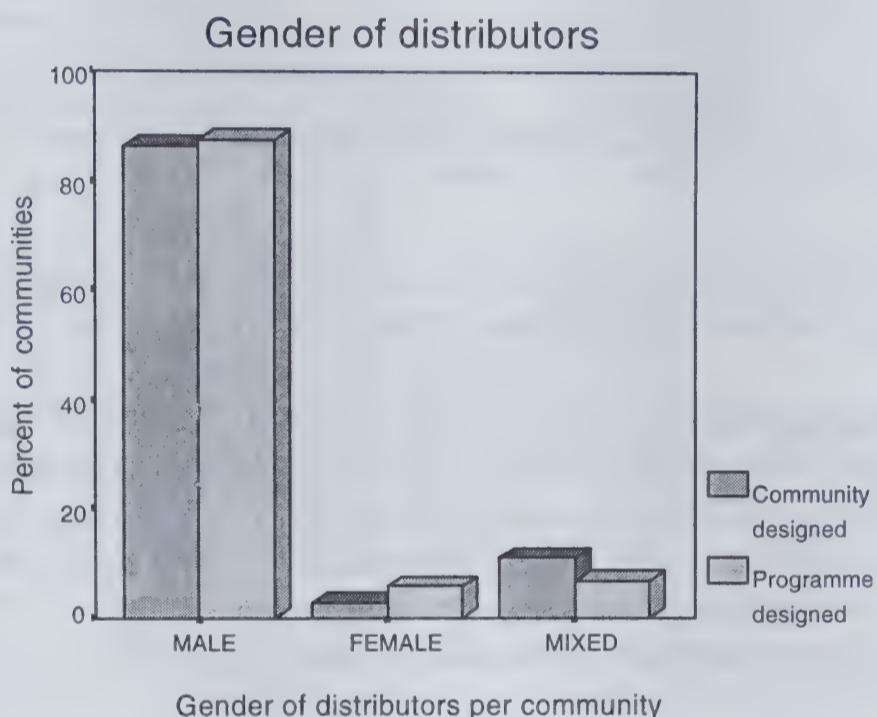
Of the many distributors in Uganda, most were farmers but a few teachers, church leaders were also involved. Most of the people selected were literate and were native to the village. In one community a local council secretary of finance was chosen and in another a fishmonger. The distributors were males except in two communities

where female distributors were selected.

In Yola the programme designed that females be selected in half the number of villages while village heads were to be responsible in the other half. However, while in the first group of villages females were indeed selected, a male was also chosen to assist the females in every village except three. In the second group of villages the village head was assisted by one or two assistants in all the villages in this category. The criteria for the selection of the assistants in the two categories were, honesty, dedication, trust and profession. Literacy was not said to be the most important factor even though in all cases one of those selected in every village was literate. All the females were farmers, had lived in the village for at least five years or are married into the village. They were all selected by the village elders or by the elders' council.

" She is our daughter, married here and a farmer like us. She is good and respectful and she will not cheat us."

In Kaduna two to five distributors were selected by each community, at least one of whom was literate. More than half of the distributors were farmers but a few other were health workers, civil servants and traders. Every community selected at least one female to assist a distributor. All the CDDs were native to the community. Trust, honesty and reliability were the main criteria used for the selection.



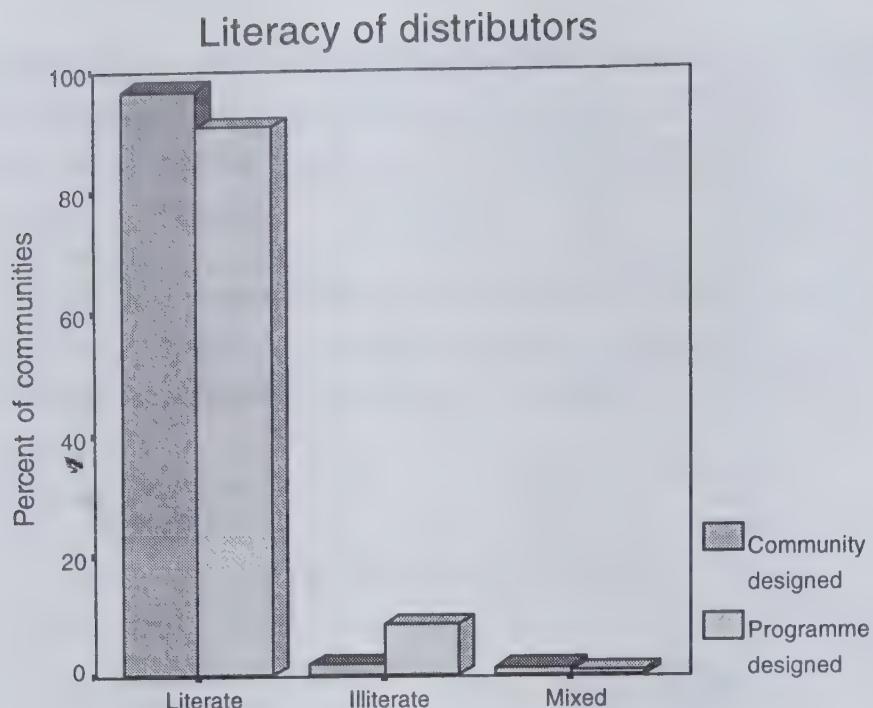
In Cameroon the health workers were the main distributors. However, many nurses had no means of transport while the few who had the means complained of lack of fuel and maintenance. Given these constraints, many nurses used UNICEF-trained community health workers to distribute the tablets in their various communities.

In Ghana, the people selected as distributors were those the community believed would accept the responsibility and perform well. In addition, consideration was given to the ability to speak particular language. Farming and teaching were the main occupations of the chosen people.

b Community-Designed

In CD, decisions on the characteristics of the distributor as well as the process of his selection were left entirely to the communities. Decisions were based on the information provided about the job description of the distributor at the time contact was made with the community by the research team.

In Uganda most of the distributors were farmers but in five communities church leaders were involved and in five others teachers were the distributors. In two villages a carpenter was chosen, while a fishmonger was selected in another village. Students and a school-leaver were chosen in three and one communities respectively. Only one community chose a female as the distributor.



"The distributors were chosen on the basis of literacy, trust and reliability, and in some cases social status". (UGANDA, IN-DEPTH).

In Enugu the most important criteria were trust, literacy, goodness, birth place and sex. All those selected were literate and were native to the village. Civil servants, teachers and students were the most frequently used distributors. In two villages health workers were selected. In all but one village, the distributors were males.

In one case in Yaba the village head's son was selected and in another case the

distributor had experience in health work. Generally however they were farmers. Two were tailors and another was an artisan. They were all native and had lived in the village for at least ten years.

In Yola the distributors were farmers in all but four cases. In one community a student was the distributor and in another a headmaster and health worker were the distributors. There was another village in which a trader was chosen and in another one, the village head assisted by one other person did the distribution. All the distributors were literate and were males except in one community where a female farmer was selected to assist male distributors. All the distributors were native to the village and were selected by the village elders.

In Mali farmers were selected as distributors in most of the villages. They were largely literate, except in four cases where trust was the principal criterion for selection and illiterate persons were selected. Health workers, including two females were selected in four villages. Distributors were involved in many other village community-based activities. Some were trainers in the literacy classes and were involved in local revenue collection as well as being secretaries of village development committees.

In Cameroon most of the distributors were farmers but were all literate. In some communities the distributor was either a teacher, a student, retired civil servant, the town crier, the village head's assistant or an artisan. All the distributors were males except for one female. The distributors were nominated on the basis of trust and confidence.

In Ghana the distributors were mostly farmers. They were natives and were literate. In one village a teacher and a trader were selected. Some distributors were church elders or village committee members.

In Kaduna the distributors were all male farmers and were literate. In one village a teacher and a member of the village health committee were selected. The criteria for selection were good character, confidence and being native to the community.

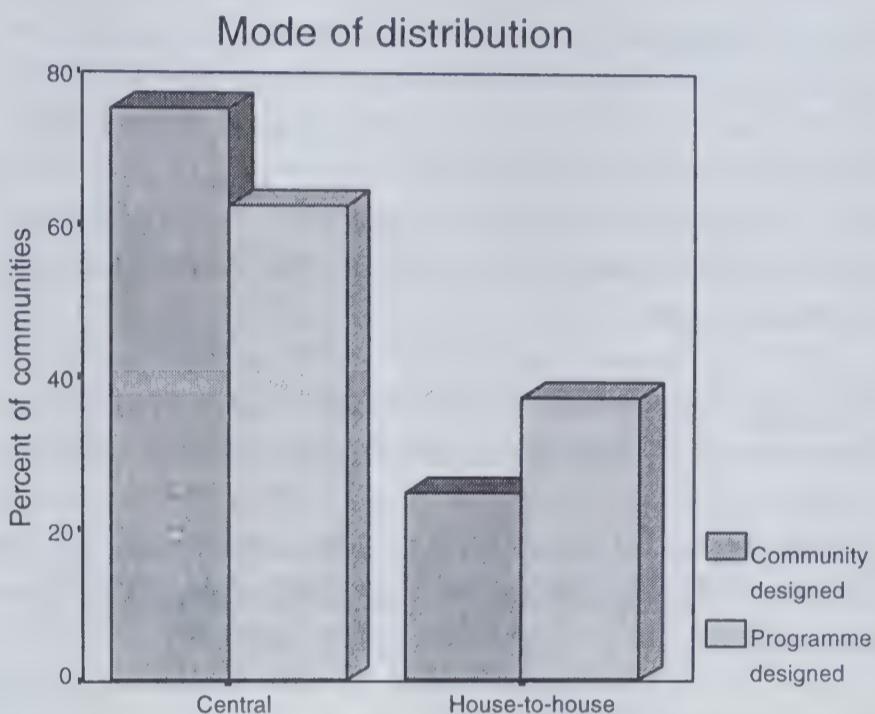
c Concluding remarks

The criteria for selecting the distributors in both the CD and PD was similar irrespective of site and village. These were mainly trust and confidence of the community in the person selected to distribute

the drug. The other criteria were the ability to read and write in the local language, being indigenous to the community and willingness to serve.

4.2.2 MODE OF DISTRIBUTION

The communities adopted different modes of distributing the drug to their members. These modes are classified into two main types on the basis of whether the people gathered in one place or the distributor had to move around to meet them in their locations. The term HOUSE TO HOUSE is used to describe a situation where the distributor moves from house to house to treat the individuals in their own houses. CENTRAL mode of distribution describes a situation where the community assembled in one particular location to receive treatment with the drug. In this mode the distributor stays in one place to treat the people. The location for 'Central' distribution varied from one site to the other, and within sites, there were variations between communities. The location often reflected the leadership structure (village head's house in Yola, Kaduna, Ghana and Yaba), community's religious inclination (the church premises in Uganda) or the relevance and value of its social infrastructure (village centre in Uganda and Mali; market in Cameroon; health centre in Mali and Ghana) or in the distributor's house (Enugu, Cameroon, Uganda and Mali).



a Programme-designed

In PD each research team designed its community treatment programme and proposed it to the community. These designs were either house to house or central (without specifying the location).

In Uganda, Mali and Enugu, the mode of distribution proposed by the control programme was the central point mode of distribution, and the locations were the distributor's house, village centre, the church or social gathering. In a few cases, distribution was changed to house to house or a combination of both house to house and central point distribution.

In Cameroon, the study followed the national programme in which head nurses from the health centers go out to the communities on schedule for outreach activities like vaccinations, health education, environmental sanitation, MCH, etc. Ivermectin distribution was integrated into these outreach activities. However, the researchers modified this system by increasing the frequency of out reach activities in the study villages.

In Yola and Kaduna the house-to-house mode of distribution was proposed to the communities. In half of the PD villages in Yola the village head was appointed as distributor by the programme. However, in most of these villages the people changed it because it conflicted with their culture. People would rather go the village head's house than for him to go out to distribute from house to house.

In Yaba, and Ghana, no specific mode of distribution was recommended by the programme, and as a result there was a fair balance between the house to house and the central point modes of distribution.

b Community-designed

In CD the mode of distribution varied from one village to the other. The central point was used in many villages. In the central point approach, the people gathered in the village centre, the village head or an elder chief's house, distributor's house, local councillor's house, dispensary or church.

In Yola, Uganda, Mali, Yaba, Ghana and Cameroon the method of distribution was predominantly central point except in a few villages where the house-to-house mode was adopted. In Yola and Yaba, the commonest central place was the house of the village head. The distributor's house was used in only three communities in the Yaba site and the only village in the Yola site that did not use the house of the village head used the dispensary. In the other sites, there was a good mix of different places that included the house of the village head, the distributor's house, the health centre or dispensary and the market place.

In Enugu, the method of distribution was predominantly house to house. In a few communities (a maximum of three in each site) distribution took place in the distributor's house.

A fairly balanced combination of the central and the house to house methods of distribution was achieved in Kaduna. As in other sites, the central locations included the distributor's house, the market place and the house of the head of the village.

c Concluding remarks

Even though the house-to-house mode of distribution was relatively more frequent in the PD villages, no single method of distribution was characteristic of either CD or PD. There were variations in both rounds of treatment and from village to village. The selection of the mode of distribution (central or house to house) was for reasons of convenience and norms which were specific to the village concerned.

4.2.3 PROCUREMENT OF IVERMECTIN

Ivermectin was procured in almost all cases from the district health office/centre nearest to the community. In PD the drug was conveyed to the communities as pre-arranged in the study design. In the original study design, it was planned to have the drug delivered by the control programme to all PD villages. However, following the very positive results of the pilot study which showed that communities were very willing and capable to collect the drug themselves from a central store at the district level, several teams decided to incorporate this option in their PD villages. Thus arrangements for conveying the drugs to the communities with programme designed distribution system varied across sites. While in some PD villages, the arrangement was for the distributors to collect the drugs from the district/local health office, in others, the arrangement was for the research team (or the NGDO representative as in the case of Mali) to bring the drugs to the communities. In CD, all communities made their own arrangements for collection of the drug.

a Programme-designed

Two major approaches were used to get the drugs to the communities from the district or local government health offices. In the first approach, the distributors, selected by the village, travelled to the district or local government health offices to collect the drug. This approach was adopted in Yola, Kaduna, Yaba, Enugu and Ghana. In Enugu, the collection point was the house of the traditional head of the district.

In the second approach, the drugs are delivered to the communities by the appointed representatives of the executing agency, health personnel or the research team. This approach was adopted in Uganda, Mali, Cameroon, and during the first round of treatment in Ghana. In these sites, the responsibility to get the drugs to the communities rests on people who did not necessarily reside in the communities.

b Community-designed

The means of getting the drug to the communities from the district or local government health offices to the communities is identical across the sites. The distributors travelled to these central points to collect the drugs. The distributors were usually informed about the availability of drugs at the district or local government health office through messages sent to them from the local health office or through regular visits to the health office. While several communities contributed some money to offset the transport costs of the distributors, in some communities, the distributors refused such offer. The qualitative data reveal that the distributors went to the district health offices by any means of transport to collect the drugs. For instance, in Cameroon, the distributors used either the public transport or travelled by the motor cycle. And in Kaduna "They decided to trek to the local government headquarters to collect the drug for the village" (OBS, KADUNA)

4.2.4 CHANNELS OF COMMUNICATION

Mobilization of the community for the programme involved, among other things, informing the people about the availability of the drug and how it would be distributed (either from house to house or from a designated central point), as well as the identity of the distributors. The channel of disseminating information varied from community to community and from site to site. The commonest channels and modes of communication were: town-criers through beating of gongs, or occasionally drums; orally from the village heads through the village chiefs or sectional heads like ward heads and heads of households; through announcements in public places or at public gatherings like the church, and by the selected distributors going round the village to pass on the message. In one instance in Cameroon, health staff located in the community helped to disseminate information.

The Table below summarises the communication channels used to mobilise and inform members of the communities about the CDT programme. There were no major difference within sites.

The method used in informing the community was village-specific irrespective of whether it is in CD or PD area. The communities in both the CD and PD used the locally available and usual method of disseminating information from its leaders to members of the community. In each case information was effectively circulated within the community.

Channels of communications used by communities

Channel	Cameroon		Ghana		Enugu		Kaduna		Mali		Uganda		Yaba		Yola		
	PD	CD	PD	CD	PC	CD	PD	CD	PD	CD	PD	CD	PD	CD	PD	CD	
Town crier		X			X	X	X		X	X						X	X
Church					X	X						X	X				
Village head											X	X	X	X	X		
Distributor			X		X		X				X		X			X	
Village Head through Chiefs or Section/Household Heads	X								X								
Health Staff	X																

PD = Programme-designed CD = Community-designed

4.2.5 TREATMENT PROCEDURES AND REFERRAL OF SEVERE ADVERSE REACTIONS

The standard method for determining dosage in all sites was measurement of height of the individual to be treated by the distributor. Calibrated sticks, usually bamboo, were most commonly used in the majority of the sites. The alternative method was to mark the various dosage heights, corresponding to half, one, one and a half and two tablets, on the wall of the house from which central drug distribution was being undertaken.

In the majority of communities and irrespective of whether distribution was from a central point or from house to house, the distributor gave the prescribed dose of ivermectin to the recipient with a cup of water, and made sure that the drug was swallowed in his presence. Sometimes, water was made available at the location of treatment, and on other occasions, as in some communities in Kaduna, the CDD went from house to house with kegs of drinking water.

In both CD and PD, arrangements were made for the management of adverse reactions. When these reactions were mild the distributor reassured the individual concerned that the effect would be temporary. When the reactions were more troublesome, did not abate readily and no improvement was noticed with time, the victims were referred to the nearest health facility.

A more detailed account of the frequency of and how adverse reactions were handled is given in section 4.

4.2.6 COST SHARING

A few communities in the study sites had programmes aimed at offsetting part of the costs of ivermectin distribution. The programmes were initiated either by the health services (as in the cost recovery programme in Cameroon) or through a joint decision of the village heads and the distributors.

In 50% of the CD villages and 50% of the PD villages in Cameroon, the official cost recovery programme was applied in which individuals were requested to pay 100 FCFA per treatment dose. Treatment was conditioned on the payment of the levy and individuals who were not able to pay the levy were not treated.

In other villages outside of Cameroon with evidence of cost sharing, there were no official policies of cost recovery. However, in order to meet the costs associated with (I) the transportation of the drugs from the district/local government health offices to the communities, and (ii) the purchase of reporting materials (note book, pens/pencils), village elders and the distributors in these villages took the decision to levy their members. Members were asked to pay a token amount of money either before treatment or after treatment. A few villages in the Kaduna and Enugu sites fell into this category. In a response to the question on the contribution of the community members to the distribution of ivermectin, members of a focus group in a village in the Enugu site had this to say:

"We are already paying for the drugs..before you collect the drug, you have to pay something"

In another village in the Enugu site, member of a focus group said:

"We collected our drugs after paying N5.00..we cannot help more"

The official and the non-official policies of collecting money to offset part of the cost of ivermectin distribution are referred to as cost sharing.

4.2.7 SUPERVISION

In line with the methodology, the Community Designed villages (CD) and the Programme Designed villages (PD) were each divided into two groups. Each 50% was to have minimal supervision by a government health official at level closest to the community and the other half was to have no supervision.

Definition:

Minimal Supervision: Implied the supervisor will contact the community only on two occasions during the period of distribution:

- (a) During initial contact with the community at the time of training and
- (b) After the agreed upon period of distribution to review the record keeping and give feedback.

The task of the supervisor was to review the ivermectin inventory form to see if this was being kept correctly, to check if the distributors were adhering to exclusion criteria, ascertain if appropriate dosage procedure was being followed and lastly to look at their records to see if this is being kept in a way that will provide the required minimum information.

No Supervision implies that after the initial approach to the community, there will be no more contact by either the researcher or the government health officials with the communities until the end of the study except when the community comes to collect ivermectin for the second round treatment or someone was dropping it off.

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Of the 272 villages in all sites, 128 had no supervision while 142 had minimum supervision. This qualitative data confirm that some form of supervision was carried out in the corresponding number of CD and PD villages, for example

"We were visited from Idah by the supervisor, Mr Peter. This community was supervised by the health officer from the Local Government Health Department" (Village summary, CD, Kaduna).

"The committee chairman and the doctors have been checking my books and helping me". (IDD, CD, Ghana).

"Chief Ugwueze (Village head) was the supervisor. He helped oversee the distribution of the drugs. (OBS, PD, Enugu).

"Minimum supervision was given by the district primary health care coordinator" (Village summary PD Cameroon).

Nature of Supervision:

This varied from sites where supervisors checked the record keeping of books, and kept a watchful eye over the tablets to where they actually performed the task specified in the protocol. Some statements from some villages support this; for example, in a PD village in Kaduna, it was stated that

"The supervisor emphasized to them (the distributors) the need to provide accurate records which they did" Village summary.

In Uganda observation notes it was said that in a CD village, a minimum supervision area, the AFO did the supervision. They checked that the distributors adhered to the exclusion criteria, appropriate dosage, recording keeping and inventory were observed by the distributors.

Characteristics of supervisors

Basically all sites had a health officer as one of the supervisors. In two sites (Uganda and Mali) members of the research team performed the task of supervisors.

In addition to the review of records by health officials, several communities, especially in the PD villages established their own monitoring units (internal checks) to ensure prompt and fair distribution of the drugs as well as adherence to exclusion criteria. There were reports that the village heads and some health committee members took part in the supervision of the distribution exercise.

"The Madaki supervised the collection and distributions of the drugs and ensured that every eligible person got the drug" Village Summary. PD Kaduna.

"The elders followed the CDDs in their homes to check if they were selling or hoarding ivermectin tablets. They also urged the community to come in time to receive ivermectin. Some people were resisting the elders call claiming that ivermectin killed some people in a distant subcountry (Logiri 30 miles) and this made supervision difficult" Observation notes, CD, Uganda.

4.3. Changes in the system over time

Over time, modifications and changes in the distribution system were effected by both PD and CD communities after the initial experience with distribution of the drug. This was mainly with respect to the choice of distributor and the mode of distribution of ivermectin. The changes occurred most frequently after the completion of the first round of distribution. In a few cases changes were made during an on-going round of treatment.

The number of communities that changed their mode of distribution varied across the sites. There were more changes in the villages with community designed distribution system than in villages with programme designed distribution system. The initial modes of distribution were changed over time in 35 CD and 23 PD villages. Of the 35 CD villages in which there was a change, 31 changed from the central mode of distribution to the house to house mode and four changed from the house to house to the central mode. In the PD villages, only three of the 23 villages changed from the central mode to the house to house mode. The rest 20 villages (15 of which are in the Yola site) changed from house to house to central.

The decision to change the mode of distribution was usually made by the distributor, after consultation with the head of the village. The often cited reasons for the change in the mode of distribution are convenience of the people (or sometimes of the distributor) and the need to ensure good coverage which was perceived to be unattainable under the initial distribution mode. In the case of Yola, however, culture plays a significant role. Since the village leaders were much involved in the distribution of the drugs, the villagers felt it was not right for the village head to visit their homes. Rather, they should go to the house of the head to collect the drug. The qualitative data from the various sites confirm these reasons. For instance, in a village in the Enugu, a distributor asserted that:

"The villagers felt reluctant to come to a central place for the distribution; therefore we decided to go from house to house" (ENUGU, IN-DEPTH).

In one of the villages in the Yaba site a distributor also asserted that:

"We first used a central point, but since the people didn't come out, we decided to go from house to house..the village head distributed first time but the second time, he appointed Dauda" (YABA, IN-DEPTH).

In a few cases the changes are brought about by the need to make the burden of distribution lighter for the distributor. For instance a distributor in one of the Kaduna villages who was trying to justify the change from the house to house mode to the central mode of distribution had this to say:

"Last year, I distributed house to house... You asked us to distribute from house to house. But this year I am distributing in my house. It is easier (more convenient for me) to distribute in my house" (KADUNA, IN-DEPTH)

5. Adherence to Appropriate Treatment Procedures

5.1. Exclusion criteria

In compliance with Merck & Co. Inc.'s stipulated directives on treatment with ivermectin, uniform training was provided on exclusion criteria to all communities (both PD and CD). Those selected as distributors were trained on the need to and how to apply the exclusion criteria and those to exclude, i.e.

- children under 5 years of age with height below 90 cm. This was to be applied mainly through height measurement, using a marked height measuring device made from local material.
- pregnant women who can be identified through observation and/or questioning.
- lactating mothers during the first week of delivery, identified through questioning and observation.
- seriously ill individuals who were identified through observation and questioning.

The ability of the distributors overall and from both types of designs (PD and CD) to adhere to training instructions as specified above, was assessed using quantitative data from the household survey backed up by quotes from qualitative data sets across sites.

5.1.1 EXCLUSION OF <5 YEARS

In the household survey, this age category (i.e. <5 years) represented 8.4% of all persons surveyed. The range of 4.8% in the Yaba site to 15.9% in the Uganda site reflects inconsistency from site to site in the representation of this age category in the surveyed population (table 5.1).

Table 5.1: Number & percentage of underfives treated by study site

Site	Number of underfives in survey	Percentage of surveyed population	Underfives treated during 2 nd round	
			Number	%
Cameroon	449	10.6	7	1.6
Ghana	284	6.8	9	3.2
Kaduna	228	8.8	11	4.8
Yaba	91	4.8	5	5.5
Enugu	116	5.7	3	2.6
Mali	305	8.3	38	12.5
Uganda	246	15.9	56	22.8
Yola	98	7.0	4	4.1

Overall, 8.6% of the surveyed children under the age of 5 years were reported to have received treatment during the study period. About 7% of the surveyed underfives received treatment during the second treatment round. The majority of those are from two sites: Mali and Uganda.

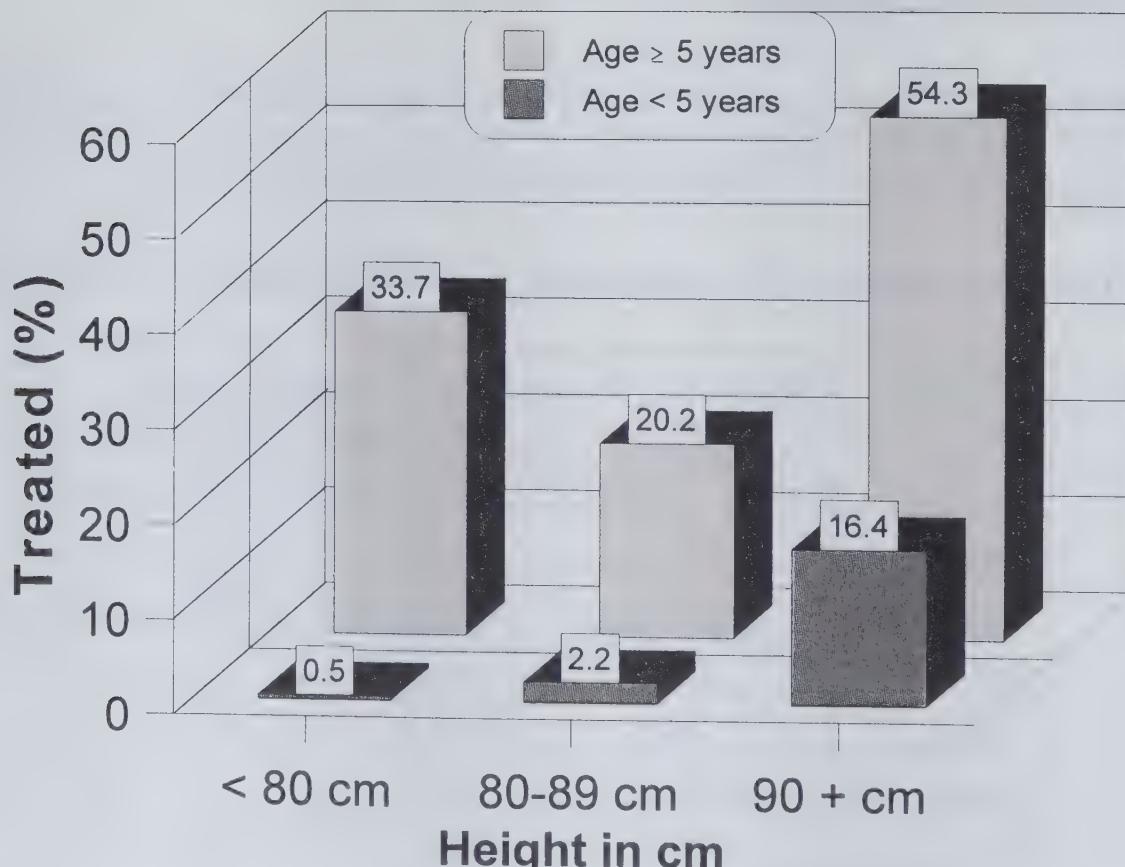
Table 5.2 gives data on treatment among under 5-year-old children by study design. In comparing the results of programme design with community design, there is not much difference in the values, 7.9% for "CD" and 6.1% for "PD" and the difference is not statistically significant.

Table 5.2: Percentage of underfives treated by study design

Design	Number of underfives in survey	Percentage of surveyed population	Underfives treated during 2 nd round	
			Number	%
CD	1053	8.1	83	7.9
PD	824	8.9	50	6.1

The treatment rates for individuals by age and height, indicates that most of those under 5 who received the drug were at least 90 cm tall. Among the underfive children with a height below 80 cm, only 2 children (0.5%) had been treated according to the information collected during the household survey (Figure 5.1).

Fig. 5.1. Treatment among children



The qualitative information shows that distributors were aware of the need for exclusion, about which they had been trained.

"We received 3 days training on using measuring sticks to determine height, apply exclusion criteria, record keeping, referral of adverse effects" - INDEPTH, PD, Yaba.

"I was responsible for giving the drug to everybody qualified to receive it, that is those who are not sick, epileptic, pregnant women and those under 5 years of age. There are up to 60 of such people" - INDEPTH, CD, Enugu.

"The leader and teachers carried out detailed health education in a church during which they emphasised the need to exclude people who were not eligible for the drug". - OBS, CD, Uganda.

Villagers were also generally aware:

" We were measured before being served. Pregnant women were not given." - He left tablets for people who had travelled and gave it to them on their return" FGD, PD, Ghana.

"Small ones did not get" - "Pregnant ones did not get" - "Children under 5 years did not get" - "We have been told that children under 5 years should not take it because it is powerful" - "Pregnant women should not take it" - FGD, CD, Kaduna.

"We have not known of such people who have not taken the tablets at all, from this area, except those who are sick and pregnant - FGD, PD, Uganda.

5.1.2 PREGNANT WOMEN

Classification of treatment rates by age and sex (Table 5.3) using the pooled data, shows lower treatment rates among females as compared to males in the child-bearing age group 15-44 years and also in the 45+ age group, while the treatment rates are higher among females in the 5-14 year age group. This could be explained by the exclusion of pregnant women, at least in the age group 15-44 years of age.

Table 5.3: Treatment rates during second round by age and sex
Percent treated (no. surveyed)

SEX	AGE		
	5-14 years	15-44 years	45 years or more
Male	52.5 (3331)	55.7 (4540)	60.3 (2125)
Female	57.5 (3070)	50.2 (5398)	55.8 (1919)

In the household survey, pregnancy was reported as the reason for exclusion from treatment in 6.5% of the women in the 15-44 year age group. The rate varied between sites with Yaba and Enugu having relatively low exclusion rates for pregnancy and Uganda a high rate of 12.5% (table 5.4).

Table 5.4: Reported reasons for exclusion from treatment among persons 15-44 years old

SITE		Reasons for exclusion from treatment	
		Sick	Pregnant
Cameroon	Female	1.2%	4.3%
	Male	1.3%	
Ghana	Female	.8%	6.5%
	Male	.1%	
Kaduna	Female	3.4%	8.3%
	Male	2.1%	
Yaba	Female	1.1%	3.1%
	Male	.6%	
Enugu	Female	1.7%	2.9%
	Male	1.6%	
Mali	Female	.5%	8.8%
	Male	.1%	
Uganda	Female	5.1%	12.5%
	Male	3.4%	
Yola	Female	2.2%	7.5%
	Male	.3%	

The qualitative data sets support the above findings on exclusion of pregnant women in the distribution of ivermectin as shown by quotes given below.

“I did not take the drug, I am pregnant, it’s after delivery that I will take it”. FGD, CD, Cameroon.

“ Pregnant women and absentees are treated later” FGD, CD, Mali.

“Pregnant women, sick people, children under five years and lactating mothers did not take the treatment.” Observation Notes, Ghana.

“All you are asking is in the book.”, “Those who are pregnant and those who were very sick did not get because they were excluded.” FGD, PD, Kaduna.

5.1.3 SERIOUSLY ILL INDIVIDUALS

Analyses of pooled data on reasons given for receiving no treatment, showed that only 1.5% of all interviewed people above the age of 5 years were excluded from treatment because of severe illness (table 5.5). Exclusion from treatment because of illness was reported for both sexes from all sites, but it was least frequent among males from Ghana and Mali, and most frequent among females in Uganda (see also table 5.4).

Table 5.5: Reported reasons for exclusion from ivermectin treatment among persons aged 5 years or more

	Reason for exclusion from treatment				Total surveyed	
	Sick		Pregnant			
	Number	%	Number	%	Number	%
Female	187	1.8%	370	3.6%	10387	100.0%
Male	127	1.3%	0	.0%	9996	100.0%
Total	314	1.5%	370	1.8%	20383	100.0%

Quotes from the qualitative data sets also indicated that distributors adhered to the training instruction of excluding seriously ill persons:

“At that time, I was sick and could not take the drug because I had been informed that sick people should not take it. It’s now I am going to take it.” FGD, CD, Cameroon.

“Sick persons, pregnant women exempt themselves and go for the tablets when they become eligible.” Observation Notes, PD, Ghana.

“Pregnant women, sick people, infants, children less than 90 cm and those who travelled.” Village Summary, CD, Yola.

“There are no people who have not taken at all except those who are pregnant and sick, and may be those who felt they were not strong enough to take the drug, after they had had the experience of the first drug.”

“Ineligible persons were generally well excluded except most young women and girls in early pregnancies were not so transparent in disclosing their ovi-status to the distributors except when the pregnancies were clearly distinct. At the same time, the reverse was also true where eligible persons were excluded from the treatment (Alio village). A dozen of people suffering from chronic bronchitis were mistaken by the CDDs as asthmatics and were consequently excluded from treatment”. OBS, CD, Uganda.

5.2. Ivermectin dosage

Distributors in both PD and CD villages were trained to determine dosage of ivermectin tablets using height measurements of the individuals. To ascertain whether they have adhered correctly to these treatment procedures, we looked at the difference between the dose taken as reported during the household survey and that calculated from the respondents height as shown below:

<u>Height (cm)</u>	<u>Dosage (tablets)</u>
90 - 119	$\frac{1}{2}$
120 - 140	1
141 - 158	$1\frac{1}{2}$
159 or more	2

The overall results of this analysis are shown in table 5.6.

Table 5.6: Correct and reported dose taken during last treatment
Percentage of those treated at least once

	Difference Between Correct Dose and Reported Dose (no. of tablets)						
	-1.5	-1.0	-.5	0	0.5	1.0	1.5
Percentage of treated	0.2	2.2	11	68.8	12.4	4.1	0.4

Table 5.6 shows the results of the first and second round of treatment with ivermectin across all sites in both programme design (PD) and community design (CD) villages combined. The majority of the study subjects (69%) have been correctly dosed and for another 23.4% the difference between correct and reported dose is half a tablet only. These findings represent a reasonable adherence to the treatment procedure by the distributors. This is supported by some of the statements retrieved from the qualitative data from most sites. For example, a participant in a female focus group discussion in a Ghana CD village said:

"After they had talked to us about the drug, they gave it out according to heights - children took $\frac{1}{2}$ tablets, others one or one and half while others had two tablets".

In Enugu, another participant in a female focus group discussion in a CD village said:

"They used measuring rulers. They distributed them according to heights".

It is interesting to note that the distributors kept this rule in mind even when the individuals were absent. A distributor in a CD village in Yaba stated thus:

"There were records of those to be treated later. I also know them and can estimate their heights to reserve their tablets". (INDEPTH)

As to the discrepancies, there could be several reasons. The reported dose may be inaccurate in a number of cases who did not properly recall the dosage received two months after the treatment. Other possible reasons are that the heights were not measured correctly by the distributor during the distribution or by the research team during the survey, or people were not measured at all and height estimates or age were used instead. Some statements from qualitative data suggest that a few distributors forgot to carry or deliberately left their measuring sticks during the treatment rounds and that they estimated the heights of the individuals visually. For example, a male distributor in a CD area of Uganda said:

"I did not use the measuring stick in the second time". (INDEPTH)

Two other distributors stated:

"I have lots of things to do, I would not measure everybody so I used the age". (INDEPTH, PD, Mali).

"I distributed using the age criteria: 0-5 nothing; 6-10 years $\frac{1}{2}$ tablet; 11-15 years 1 tablet; 16-20 years 1.5 tablets and 21 years and above 2 tablets". (INDEPTH, CD, Cameroon).

Table 5.7: Correct and reported dose taken during last treatment by study design
 Percentage of those treated during second treatment round

Design	Difference Between Correct Dose and Reported Dose (no. of tablets)						
	-1.5	-1.0	-.5	0	.5	1.0	1.5
CD	0.2	2.4	12.8	66.2	13.1	4.8	0.4
PD	0.3	1.7	8.1	68.4	15.1	5.7	0.8
Total	0.2	2.2	11.3	66.9	13.7	5.1	0.5

Table 5.7 shows the difference in correct and reported dose in all sites for CD and PD villages separately, and for the second round of treatment only. The overall result is quite similar to what was reported in table 5.7 for both treatment rounds combined, and this indicates that the distributors were consistent in their efforts to adhere to appropriate treatment procedures. There is no major difference in the pattern for CD villages as compared to that of PD villages. The PD villages have a slight tendency to overdose, but the difference is minimal.

Table 5.8: Correct and reported dose taken during last treatment by study design
 Percentage of those treated at least once

Site	Design	Difference Between Correct Dose and Reported Dose (no. of tablets)						
		-1.5	-1.0	-.5	0	.5	1	1.5
Cameroon	CD	-	2.2	4.2	70.2	17.9	5.1	0.3
	PD	-	1.0	6.3	65.4	23.8	3.4	0.3
Ghana	CD	0.2	1.6	9.9	67.7	16.1	4.0	0.5
	PD	0.2	0.6	6.1	85.0	6.2	1.5	0.5
Kaduna	CD	0.7	2.3	12.1	62.7	20.8	1.0	0.3
	PD	-	0.3	14.7	61.9	22.2	0.3	0.6
Yaba	CD	-	-	2.0	81.0	13.6	3.2	0.2
	PD	-	2.1	3.2	79.9	11.6	3.2	-
Enugu	CD	-	1.8	1.1	59.7	21.6	15.2	0.6
	PD	1.4	1.6	9.6	41.9	23.8	19.9	1.8
Mali	CD	0.2	4.0	26.6	65.3	2.2	1.1	0.5
	PD	-	5.7	8.6	75.4	5.7	2.7	2.0
Uganda	CD	-	1.6	7.2	58.5	21.7	10.2	0.7
	PD	0.2	0.6	8.2	62.3	20.5	7.9	0.2
Yola	CD	-	1.1	4.6	87.5	4.6	1.4	0.8
	PD	-	2.5	11.8	80.1	3.7	1.2	0.6

Table 5.8 shows a further breakdown of the results by sites and study design. In all sites, the dosage was exactly correct for more than 50% of the surveyed persons and this percentage varied from 54% in Enugu to 84.8% in Yola. Taking the sites individually there is no significant difference in the dosage pattern between the CD and PD villages. In 5 sites, and especially in Enugu and Uganda, there is a tendency to overdosing. In Mali and among PD villages in Yola it is the reverse with a tendency to under dosing. However, the under dosing or overdosing is mainly by $\frac{1}{2}$ tablet only, and in all sites there are only very few people for whom the difference between correct and reported dose was more than 1 tablet.

5.3. Management/referral of severe adverse reactions

According to the protocol, monitoring of adverse reactions was to be undertaken by the ivermectin distributors in the programme design method. In the community design methods the teams were to specify how monitoring for severe adverse reactions was ensured if different from monitoring by the distributors. Those with minor reactions were to be reassured only whilst those with severe reactions were to be advised to report to the nearest health facility.

5.3.1 REACTION TO TAKING IVERMECTIN

Of all the respondents in the survey who were treated during the second round, 64.9% reported that they felt better, 27.5% did not feel any difference and 5.6% said they felt worse after taking the tablets. The number of people reporting to have felt worse after taking the tablets were fairly evenly distributed across sites with the exception of Yaba where only 0.7% of respondents reported they felt worse and Enugu where more than 10% felt worse (Table 5.9).

Table 5.9: Response to taking ivermectin
Results for those treated during second treatment round

Site	Treated	Response to treatment		
		Felt Better	No Difference	Felt Worse
CAMEROON	2003	71.9	20.1	5.8
GHANA	1698	69.3	23.5	6.5
KADUNA	1194	47.6	47.2	5.3
YABA	689	96.4	2.9	0.7
ENUGU	1451	74.4	8.9	10.5
MALI	2553	61.9	32.1	4.7
UGANDA	1038	33.6	62.3	3.4
YOLA	442	73.8	14.9	8.6

5.3.2 TYPES OF SIDE EFFECTS BY SITES

Across sites the side effects encountered were mainly itching, headaches, fevers and general body pains. The few severe adverse effects reported were difficulty in breathing, dizziness and fainting.. These reactions were generally reported to the distributor or elders, and they were the same for both programme design and community design.

"I was the first person to start taking the drug here, so the first drug itched me a lot and I had a lot rashes and swellings." (FGD, CD, Females, Uganda)

"I took the tablets, got pruritus, swelling of the body and a lot of tiredness, now I feel much better." (FGD, Females, CD, Cameroon.)

Among those who reported during the survey to have felt worse after treatment, further information was collected to determine if the reaction could be classified as a severe adverse reaction. The results are shown in table 5.10. The most common potentially severe reaction reported was severe dizziness, followed by difficulty in breathing and 'fainting'. The number of potentially severe adverse reactions reported varied dramatically between sites, from 4 cases in Kaduna to as many as 132 in Enugu. It is likely that this reflects variation in the interpretation of the classification criteria by the interviewers rather than a true variation in the incidence of severe adverse reactions.

Table 5.10: Response to taking ivermectin
Results for those treated during second treatment round

	Dizziness	Fainting	Difficulty breathing
CAMEROON	47	2	5
GHANA	16	3	7
KADUNA	3	0	1
YABA	2	0	0
ENUGU	108	7	17
MALI	81	0	2
UGANDA	5	0	0
YOLA	13	0	6

5.3.3 MANAGEMENT OF ADVERSE REACTIONS

a Minor adverse reactions

During the household survey no further information was collected on the management of severe reactions and the main source of information on this aspect of the distribution system comes from the indepth interviews with distributors and village leaders, and the focus group discussions in each village. Responses from focus group discussions and indepth interviews show that most distributors in administering the drug reassured their subjects that minor side effects would disappear after a while. A village leader in Ghana said:

"They had problems like itching, swelling of the hands and feet and others but the problems were short-lived so nothing was done about it."

b Severe adverse reactions

The severe adverse side effects were first reported to the distributor and were referred to the nearest health facility when there was no improvement. That cases of severe adverse side effects were referred to health facilities is evident from the qualitative data for 4 sites: Ghana, Cameroon, Enugu and Yaba. For the other sites there was no information in the qualitative data on any referral of adverse reactions.

From the accounts on the cases which were referred to a health facility, it appears that these severe side effects were related to the severity of the common adverse reactions to ivermectin treatment, rather than the defined severe side effects of coma and difficulty in breathing.

In Ghana, 2 cases were referred in 2 villages, one in a programme design and one in a community design village. The procedure for referral was not clearly indicated, all that was said was that they reported to health facilities and got treated. Below are quotes from these 2 villages.

"Some people experienced swollen body, skin rashes and irritation. Two people went to the Health Centre on account of body." (FGD, FEMALES, CD, GHANA).

"Some of the problems people experienced were swelling of the face and limbs. For sometime some could not walk around. I know of somebody who reported at the Foso Hospital for treatment." (IDL, PD, GHANA)

In Cameroon, people reported to Health facilities in 5 villages, 2 in community design and 3 in programme design. They reported to the distributor who referred them.

"They reported to me and I had to direct them to the Health Centre." (IDD, PD, ENUGU.)

"Swollen body, rashes, headache. Some were complaining of difficulty in breathing . There were persons I referred to the clinic and they were treated." (IDD, CD, Cameroon.)

In Enugu, people in 21 communities reported to a health facility for the management of severe adverse reaction, 14 for CD and 7 for PD. They reported these reaction first to the distributors who referred them.

"The tablets was a burden on us. It caused several ailments. Some of us were admitted at hospital for more than 2 weeks after taking the drugs." (FGD, FEMALES, PD, ENUGU.)

"Some of us who had the problems were not at all that disturbed, some however consulted the distributors when the side effects persist beyond three days."(FGD, FEMALES, PD, ENUGU.)

In Yaba, only one person in a programme design village was known to have reported to a health facility because of adverse reactions:

"One person had to be taken to the hospital, others did nothing." (IDL, PD, YABA).

5.4. Concluding remarks

The available information indicates that CDD's adhered well to appropriate treatment procedures in both community-design and programme-design villages. The exclusion criteria were properly applied: children who were too young and small were not treated, and pregnant women and severely ill persons appeared to have been excluded from treatment in all study sites. The dosage given was within $\frac{1}{2}$ tablet from the correct dose in over 90% of all persons treated and dosage errors of more than 1 tablet were rare. The information on management and referral of severe adverse reactions is less comprehensive but the available information seems to indicate that severe or persistent adverse reactions are reported to the CDDs and that the CDDs refer such cases to the nearest health facility.

6. Treatment Coverage

6.1. Overall treatment coverage

The first round of treatment started around August and September 1995 and the second round took place between February and March 1996. The final evaluation was done between April and May 1996 which was about 1 to 2 months after the start of the second round of treatment. The final evaluation included the household survey in which a structured questionnaire was administered to a random sample of individuals in each study community. The questionnaire included questions about the treatment history of the person interviewed and the duration since the last treatment.

The information on duration since last treatment showed for each study site a clear bimodal distribution and the two modes coincided with the known dates of the two treatment rounds in each site. Thus, it was possible to determine for each person whether they had received treatment during the second treatment round, and whether they had received at least one treatment during the study period. Using this information, the following two indices for treatment coverage were calculated for each community:

- **Percentage of the total population treated during the second round.** This was estimated for each community by the percentage of persons in the sample who were treated in the second round, divided by the total number of people in the sample. This index provides a classic estimate of the treatment coverage during one single treatment round. Its disadvantage in the present study is that it underestimates treatment coverage in several communities because of the requirements of the study protocol which stipulated that the evaluation should take place 1-2 months after the scheduled date for the second treatment.
- **Percentage of the total population treated at least once during the study period** (also referred to in the text as the coverage for both treatment rounds combined). This was estimated for each community by the percentage of persons in the sample who were treated at least once during the study period divided by the total number of people in the sample. The limitation of this index is that it does not allow an assessment of the coverage obtained during each of the treatment rounds. However, as it is less sensitive to external problems such as temporary drug shortage, this index was considered useful for the comparative assessment of the performance of different approaches to Community Directed Treatment.

As mentioned in section 5.1.1, there was inconsistency between sites in the representation of children below the age of five years in the household survey. To correct for this in the estimation of treatment coverage, the coverage was first calculated for the population above the age of five years. Then, using the assumption that children below the age of five years represent 16% of the population and that they were not treated, the coverage of the total village population of all age groups was estimated by multiplying the treatment coverage above the age of five with a factor of 0.84.

6.1.1 STUDY POPULATION

A total of 20,383 people above the age of five years were interviewed during the final evaluation. Table 6.1 gives the number of villages surveyed and the number of persons interviewed by site and by design. The number of villages surveyed per site varied from 25 in Yola to 44 in Cameroon, and the number of persons interviewed from about 1,300 in Uganda and Yola to over 4,000 in Mali.

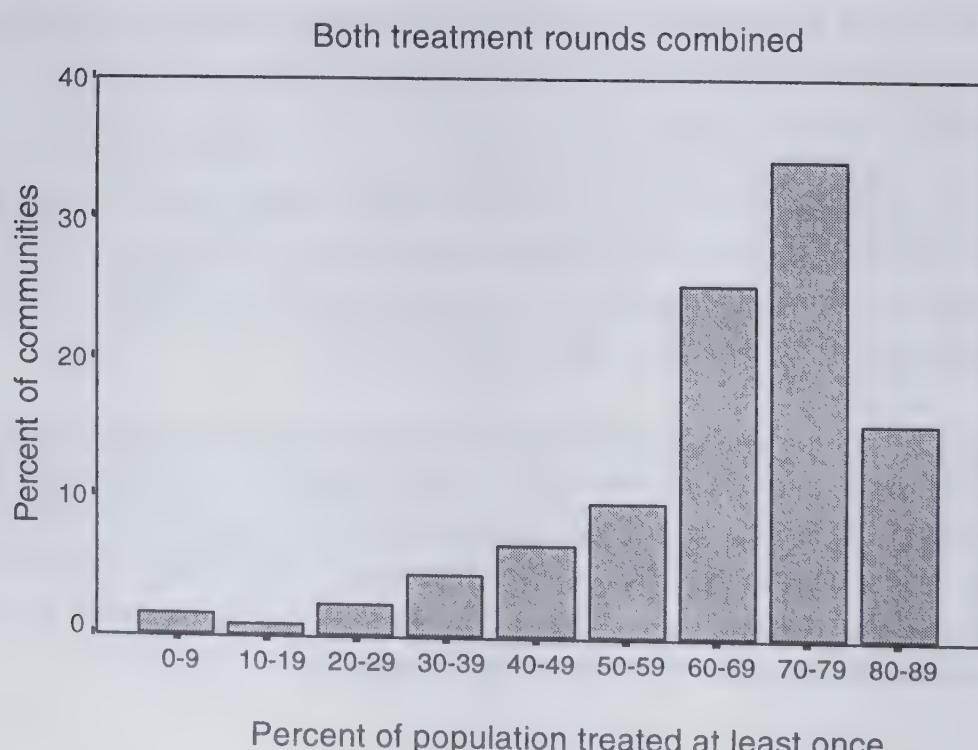
Table 6.1: Household surveys undertaken in the different study sites

SITE	Interviewed persons above the age of 5 years only					
	Community designed		Programme designed		Total	
	Villages surveyed	Persons interviewed	Villages surveyed	Persons interviewed	Villages surveyed	Persons interviewed
Cameroon	20	1746	24	2026	44	3772
Ghana	24	2285	16	1594	40	3879
Kaduna	16	1389	12	985	28	2374
Yaba	16	1046	12	772	28	1818
Enugu	16	1163	12	766	28	1929
Mali	30	3062	12	946	42	4008
Uganda	13	686	12	612	25	1298
Yola	18	602	19	703	37	1305
Total	153	11979	119	8404	272	20383

6.1.2 TREATMENT COVERAGE FOR BOTH ROUNDS OF TREATMENT COMBINED.

Figure 6.1 shows the distribution of the treatment coverage per community for both treatment rounds combined. In 75% of the communities, the treatment coverage was between 60% and 84% of the total

Fig. 6.1: Treatment coverage

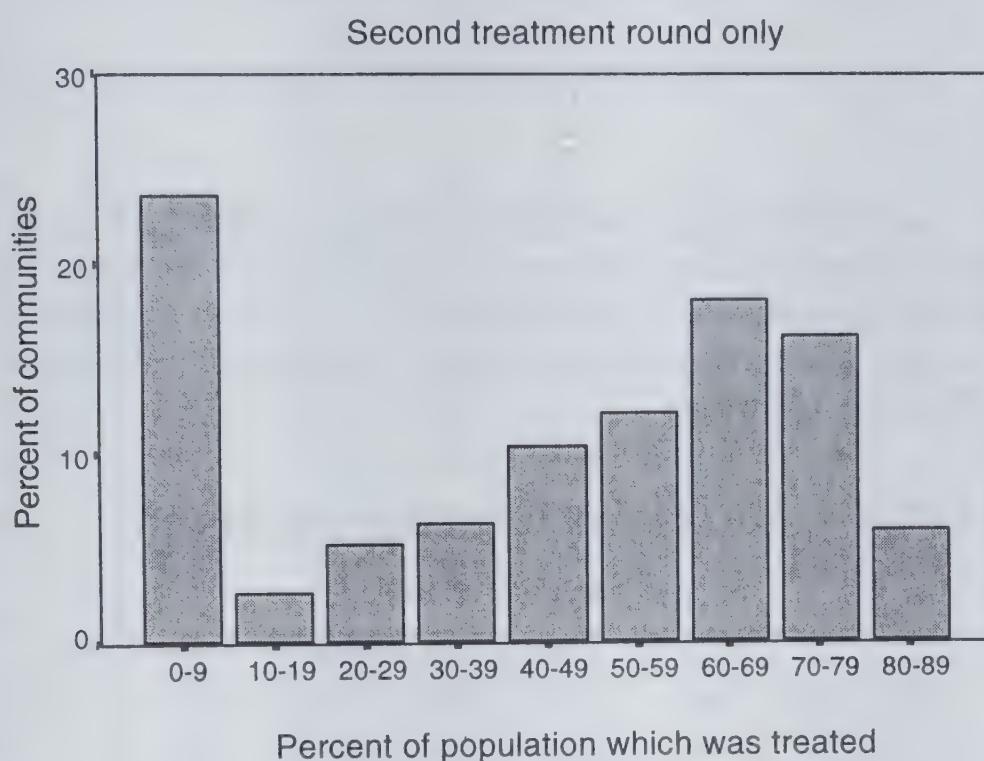


population, and in half of the communities the coverage was even above 70%. However, the distribution of treatment coverage is very skew to the left and in 15% of the communities the coverage was very poor with between 7% and 40% of the population treated during the total study period.

6.1.3 TREATMENT COVERAGE FOR SECOND ROUND OF TREATMENT ONLY.

The distribution of treatment coverage during the second round of treatment is given in Figure 6.2. Compared to the distribution for both treatment rounds combined in Figure 6.1 there are some major differences. Overall the coverage is much lower and only 40% of the communities have a treatment coverage of more than 60% of the total population. This is of course partly due to the fact that this index refers to one treatment round only, but it is also a result of the strict evaluation schedule which did not take into account individuals and communities that were treated after the evaluation but before the next treatment period. A particularly striking difference is the large group of 64 communities (24% of all communities) where the coverage was close to or equal to zero.

Fig. 6.2: Treatment coverage

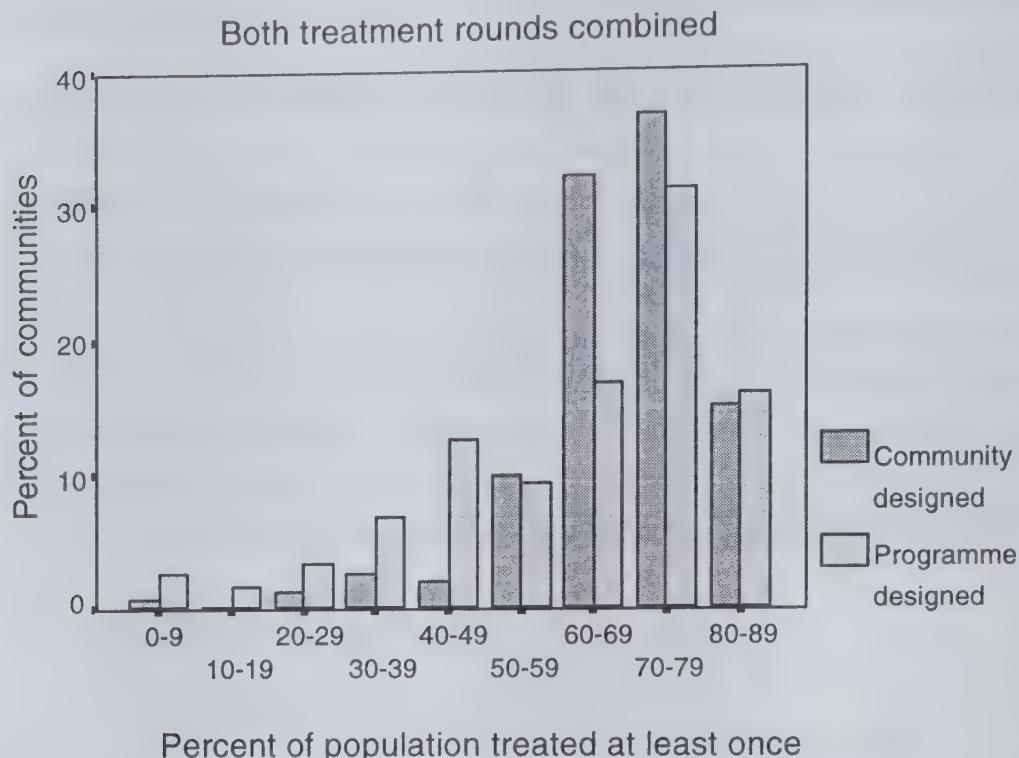


Various explanations for the observed variations in treatment coverage will be discussed in chapter 7.1.

6.2. Treatment coverage by study design

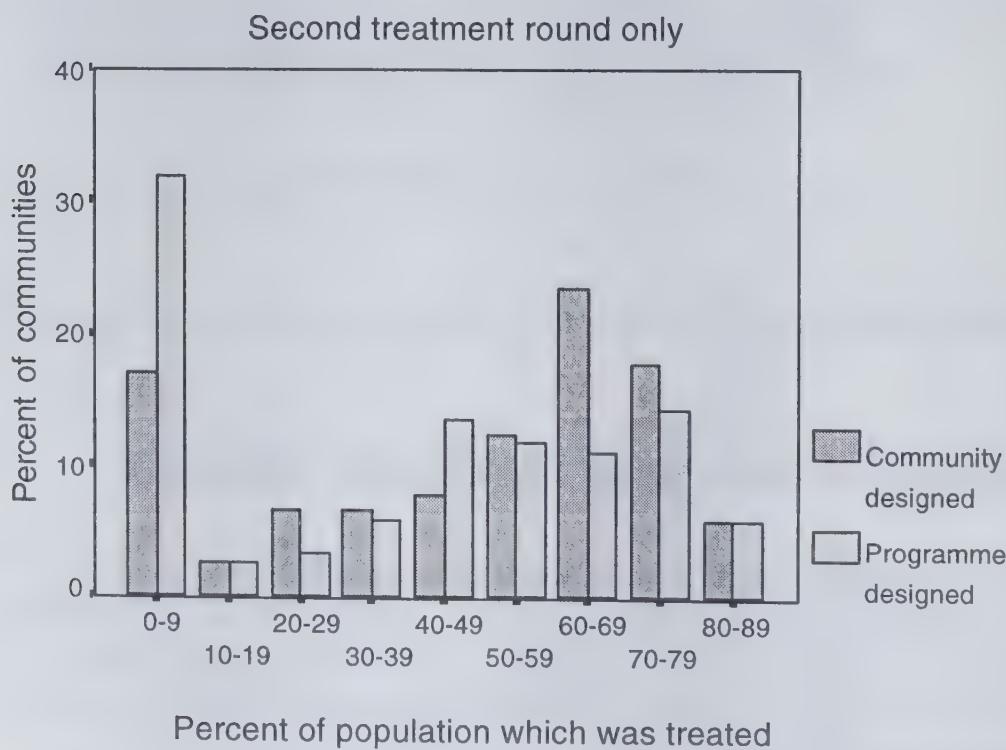
Figures 6.3 and 6.4 show the distribution of treatment coverage by study design for both treatments combined and for the second treatment respectively. In both cases, the treatment coverage in the programme design villages is lower than in those with a community design, and the difference is statistically significant in both cases (Mann-Whitney test: $p<0.001$ for both treatments combined and $P<0.05$ for the second treatment).

Fig. 6.3: Treatment coverage by design



The villages with less than 50% coverage for both treatments combined (Fig. 6.3) are predominantly programme designed villages. For the treatment coverage during the second round (Fig. 6.4), the programme designed villages are more frequently found in the lowest treatment category of 0%-9% coverage. For both indices of coverage, the community designed villages are more prevalent in the range of 60%-80% treatment coverage.

Fig. 6.4: Treatment coverage by design



6.3. Treatment coverage by study site.

Table 6.2 summarizes the treatment coverage by study site and study design according to both indices. For both treatment rounds combined the mean treatment coverage for the study was 65.8%, ranging from 51.5% in Yola and 57.5% in Cameroon to 74.7% in Yaba and 76.5% in Mali. During the second round, the treatment varied from 28.2% in Yola to 63.4% in Uganda. The difference in coverage patterns by site is better illustrated in the box-plots in Figures 6.5 and 6.6.

Treatment coverage per village (as % of total population)

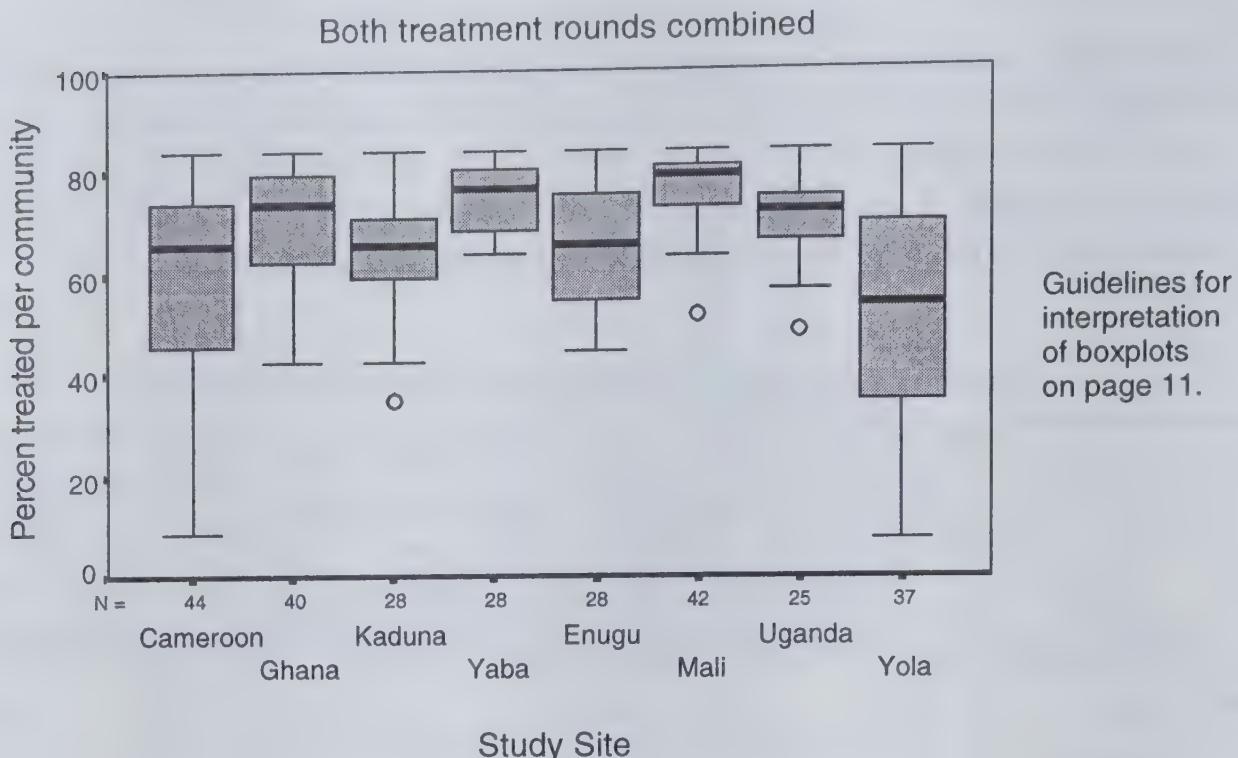
SITE	Distribution type									
	Community designed			Programme designed			Total			
	N	Mean treatment coverage	SE of mean	N	Mean treatment coverage	SE of mean	N	Mean treatment coverage	SE of mean	
Second treatment round only	Cameroon	20	42.1	4.8	24	46.7	5.5	44	44.6	3.7
	Ghana	24	34.2	5.4	16	39.9	7.8	40	36.5	4.4
	Kaduna	16	55.3	5.1	12	25.3	7.0	28	42.4	5.0
	Yaba	16	31.7	9.4	12	31.5	11.3	28	31.6	7.1
	Enugu	16	68.5	2.5	12	53.6	2.4	28	62.1	2.2
	Mali	30	57.6	4.9	12	35.2	11.0	42	51.2	4.9
	Uganda	13	64.3	2.3	12	62.5	3.4	25	63.4	2.0
	Yola	18	38.1	6.3	19	18.7	5.6	37	28.2	4.4
	Total	153	48.4	2.2	119	38.7	2.7	272	44.2	1.7
Both treatment rounds combined	Cameroon	20	57.4	4.2	24	57.6	5.0	44	57.5	3.3
	Ghana	24	67.9	2.3	16	75.0	2.6	40	70.7	1.8
	Kaduna	16	68.7	2.1	12	57.0	3.6	28	63.7	2.2
	Yaba	16	75.2	1.6	12	74.0	2.1	28	74.7	1.3
	Enugu	16	69.7	2.5	12	57.7	3.2	28	64.5	2.2
	Mali	30	76.2	1.1	12	77.1	2.5	42	76.5	1.1
	Uganda	13	70.1	1.2	12	69.6	3.0	25	69.9	1.5
	Yola	18	61.6	3.9	19	41.9	4.7	37	51.5	3.4
	Total	153	68.6	1.0	119	62.2	1.6	272	65.8	1.0

For both treatments combined (Fig. 6.5), the highest treatment coverages were obtained in Mali and Yaba, and in both sites the range between minimum and maximum coverage per village is small. Very different patterns were observed in Yola and Cameroon, which had not only the lowest median coverage but also the widest range in coverage per village, each site with the lowest coverage below 10%.

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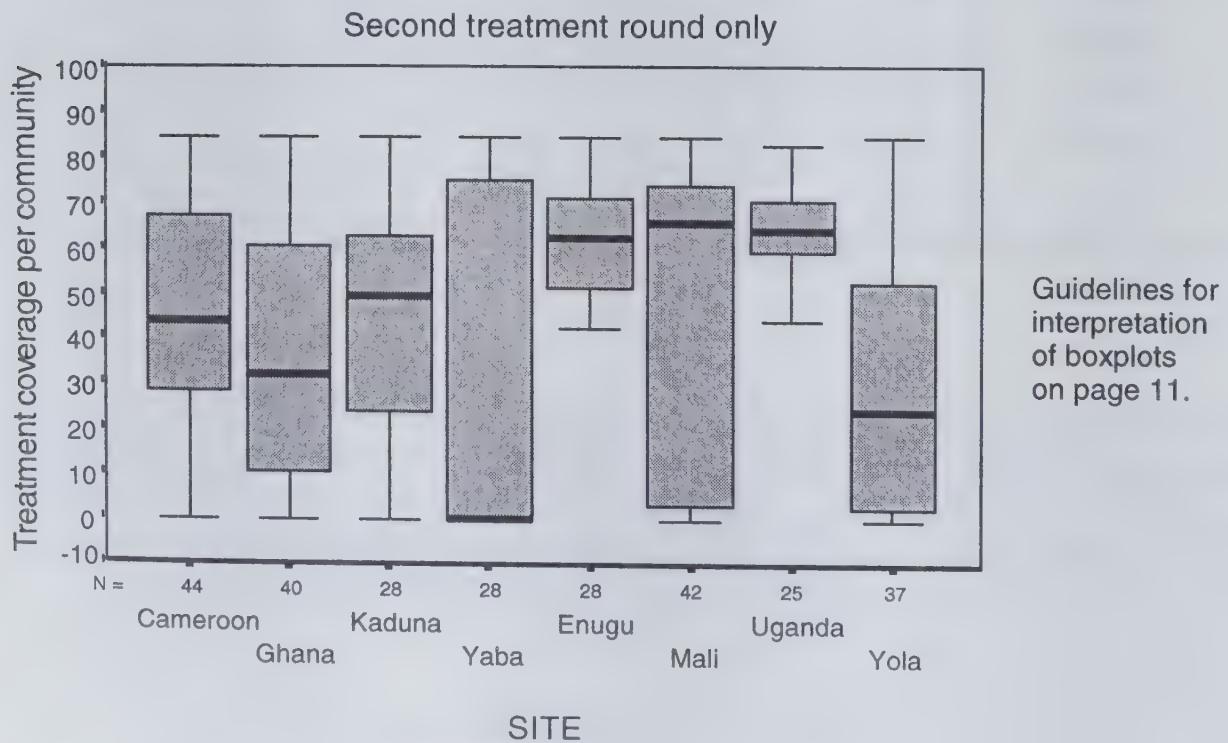


Fig. 6.5: Treatment coverage by site



The patterns for the second round of treatment are very different for most sites (Fig. 6.6). While Yaba had a high coverage for both rounds combined, for the second round of treatment more than half of all villages had zero treatment coverage. Five of the other sites had also communities where nobody was treated during the second round. The only exceptions were Enugu and Uganda.

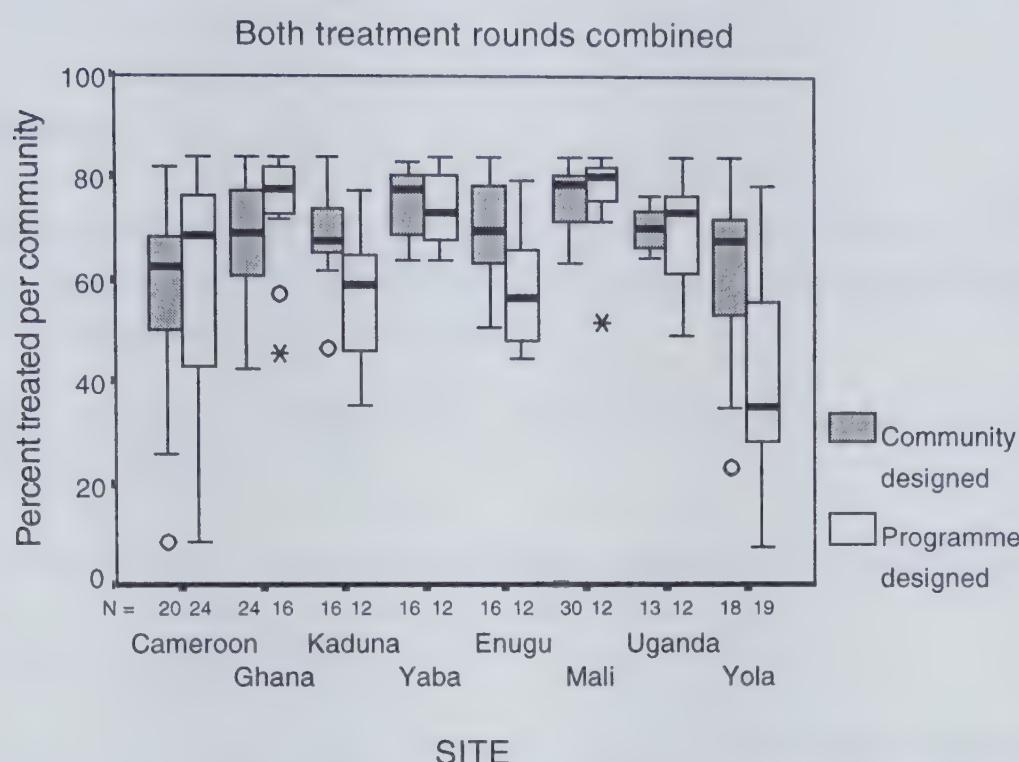
Fig. 6.6: Treatment coverage by site



6.4. Treatment coverage by site and design

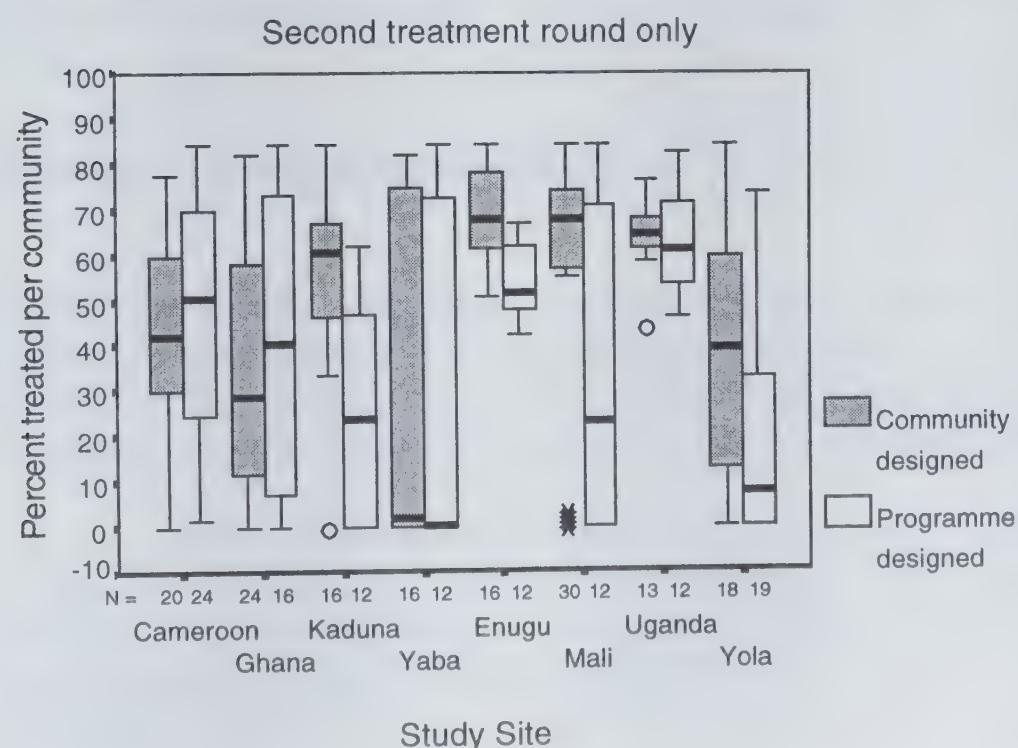
The distribution of treatment coverage by site and design is shown in Figures 6.7 and 6.8 for the two coverage indices. The treatment coverage is clearly lower in the programme design village in three sites: Kaduna, Enugu and Yola. Only in Ghana does the reverse seem to be true.

Fig. 6.7: Coverage by site and design



During the second treatment (Figure 6.8) the programme design villages had lower coverage than the community design villages in the same three sites of Kaduna, Enugu and Yola, but now also in Mali

Fig. 6.8: Coverage by site and design



where there were several villages with zero coverage among the programme design villages.

To explain the differences in treatment coverage described in this chapter, a detailed analysis of the qualitative data was undertaken. The results of this analysis are presented in chapter 7.

7. Factors related to Treatment Coverage

7.1. Comparison of communities with high, low and zero treatment coverage

7.1.1 INTRODUCTION

An important feature of the findings from this study is the wide variation in the levels and patterns of treatment coverage within the study areas. Three coverage patterns which are particularly significant to our study are examined in this section. They are:

- (1) Zero treatment coverage in the second round of treatment irrespective of coverage in the first round of treatment
- (2) Low (<50%) overall coverage, but not zero coverage in the second round
- (3) High overall coverage (>75%)

Qualitative data from the study are used to determine the factors that might explain these patterns in each of the study sites where they were observed. In doing so, however, it should be noted that the low coverage levels at the second treatment round could be a product of the strict evaluation schedule of the researchers which did not take into account activities and competing priorities of the villagers. Also, individuals who might have taken the drug shortly after the evaluation period were classified as not treated, and communities that treated after the evaluation date were classified as having zero coverage in the second round treatment. This suggests that in many cases our measure of coverage for the second treatment round is an underestimate.

7.1.2 ZERO COVERAGE IN THE SECOND ROUND

At the time of the final evaluation, 42 villages across the different sites were yet to have the second round treatment and hence were classified as having zero coverage. The number of such villages varied by site: Yaba had 15, Yola 9, Mali 8, Kaduna 5, Ghana 4, and Cameroon 1. There were no villages in which the second round treatment had not started in the Uganda and Enugu sites.

The main reasons that were identified for the zero coverage level in the second round are the lack of any or insufficient supply of ivermectin at the district or local government headquarters, failure to get the tablets to the villages from the central source, and local priorities, like the need to complete harvesting in these agricultural communities, that led some communities to postpone the distribution to a more appropriate period.

During the study period, there was a serious shortage of ivermectin in Nigeria. To enable the study to be completed as scheduled, Merck & Co, through its humanitarian programme, made a special shipment of ivermectin available for the Nigerian study sites. Unfortunately, when this special shipment arrived at the airport in Lagos, it took several months to get it cleared through customs and forwarded to the study sites. Three of the study sites, armed with the information that the drug was forthcoming, managed to borrow ivermectin from NGO's working in onchocerciasis control or from the national control programme. Through this mechanism, Kaduna and Enugu managed to obtain an adequate supply of ivermectin, while Yola managed to borrow only part of the required amount. In Yaba there was no such temporary solution and the treatment had to await the arrival of the special shipment of ivermectin.

The study villages in the Yaba site are under two different Local Government Areas which received their shipment of ivermectin for the second treatment round at different times. In one Local Government headquarters, the drugs were received early enough for the communities to proceed with treatment. However, the local government headquarters from which the 15 zero coverage villages in the Yaba site were expected to collect their drugs took delivery of the second-round treatment drugs less than a week before the commencement of the final evaluation. Distributors in these villages did not know of the availability of the drugs at the local government headquarters until they were informed by the research team during the final evaluation. The distributors went to the local government headquarters to collect the drugs only after the final evaluation had been completed. In one or two of these villages where the drug had already been collected from the local government headquarters before the research team got to them for the final evaluation, the local distribution had not yet started. Owing to the strict schedule of the evaluation, all these villages were classified as having zero treatment coverage in the second round.

In Yola, non-availability of drug was the major factor for zero coverage in the second round; only 2 of the 9 villages with zero coverage at the Yola site had any ivermectin available from the local government headquarters. Although local distributors for the remaining 7 made several trips to try to get the drugs for their villages, they received none.

A combination of local catastrophe and features of the local distribution system delayed the second treatment round in some villages at the Kaduna site until after the evaluation phase. A distributor in one village had been murdered, and because he had been appointed according to the criteria of a programme-designed system, the rigidity of the distribution system also required that the community should wait until after the evaluation when the programme officials appointed a replacement.

In another PD village in the Kaduna study area, five people, including the nephew and sister of the village head (Madaki) died at the time of collection. The people postponed the distribution, explaining that, "We cannot come out to do anything now since Madaki is mourning". In a third PD village of the Kaduna site, the two distributors were arrested and detained for murder. Because no substitutes had been appointed while they were detained for three months, their absence delayed the collection of ivermectin from the local government headquarters.

At four Ghanaian villages, even though distributors had collected the ivermectin from the district, they decided, on the advise of the communities, to delay distribution until after the farming season. The villagers feared that adverse reactions, which some had experienced after the first treatment round, might interfere with their work, and so they postponed the second distribution.

In Cameroon and Mali the delays were not so deliberate. In six villages with a programme-designed system in Mali the lack of second-round treatment resulted from the failure of the appointed officials of the executing agency to deliver ivermectin to the villages. Although the communities might have wanted to send their own representatives to the district to collect the drug, they could not do so because the operating rule of the agency is that the drugs could be brought to the communities only by their officials. The officials could not be replaced by the communities. In another village with a community-designed system, however, when a distributor left the village to look for work in the city, he was replaced. Unfortunately, the final evaluation was concluded before the new distributor went for the collection of the drugs from the district.

Inability of the distributor to understand the appropriate treatment interval appears to have caused the delay in one village in the Yola site. In explaining why the second round treatment has not started in his village the distributor said:

"Distribution has not taken place because it is not yet a year after we received the first consignment".

7.1.3 LOW COVERAGES IN BOTH ROUNDS

A village in which treatment coverage is non-zero but lower than 50 percent in both rounds combined is classified as a low coverage village. At the time of the final evaluation, there were 36 villages across the various study areas in this category. Cameroon tops the list with 14 villages, 10 of which had the programme designed distribution system. The number of the low coverage villages in the Yola, Kaduna, Enugu, Ghana and Uganda sites are 11, 4, 4, 2 and 1, respectively. In the Yola, Kaduna and Enugu sites, 8, 3 and 2 villages are those in which the distribution system was designed by the programme.

Three major factors explain the low treatment coverage across sites: insufficient supply of ivermectin at the district level and consequently at the community level, motivation of distributors, especially in the programme designed villages and cost recovery, particularly in Cameroon.

In all the Nigerian sites (Yola, Kaduna and Enugu), the major cause of the low coverage is inadequate supply of ivermectin. In Yola, for instance, the usual complaint in all the villages was that the number of drugs collected from the local government headquarters was far below the number required to meet the demand of the people. As a result of the gross inadequate supply of the drugs in some villages, the distributors, usually with the advice and support of the village leaders, devised unconventional means of distributing the drugs in order to ensure that all families (not individuals) benefit from the available supply. In one of the villages in the Yola site, a decision was taken to treat only two people per family "so that all families can benefit from the distribution". In another village, the tablets were distributed only to males and yet in another village, the drugs were distributed to those who paid tax.

In Yola, the distributors from both the programme designed and community designed villages were expected to collect their drugs from the same source: the local government headquarters. By having a preponderance of villages with programme designed distribution system in the low coverage category, our findings tend to suggest that the distributors from the community designed villages tend to react more quickly to the information about the availability of drugs at the local government

headquarters. They appear to get more from the available supply at the headquarters than their counterparts in the programme designed villages who might have come much later.

In Cameroon, all the distributors in the 10 low coverage villages with programme designed distribution system were government workers (nurses) majority of whom resided outside of the villages. They resided in the district headquarters from where they paid scheduled visits to the villages. Ivermectin tablets were usually distributed during such visits and members of the communities who were absent from the villages during the visits would not receive the tablets. The scheduled visits were often interrupted by lack of transport to the villages, thus further reducing the chances of the villagers receiving ivermectin. The salary cut in Cameroon also affected the morale of the distributors and consequently reduced the number of times they visited the villages to distribute ivermectin.

In addition to the problem of motivation of the distributors, it was also observed that coverage was generally lower in communities with cost recovery programme. The two community designed villages in the low coverage category in Cameroon have the cost recovery programme.

7.1.4 HIGH COVERAGE IN BOTH ROUNDS

At the time of the final evaluation, there were 37 villages in which coverage levels are 75 percent and above in the two rounds of treatment combined. The 37 villages are distributed across the various sites as follows: Mali (8), Yaba (7), Enugu (6), Ghana (6), Cameroon (5), Kaduna (2), Uganda (2) and Yola (1). Six of the eight high coverage villages in Mali and all the six villages in Enugu had community designed distribution systems. The number of high coverage villages with community designed systems in Yaba, Ghana, Cameroon, Kaduna, Uganda and Yola are 4, 3, 1, 2, 1 and 1, respectively.

Across sites, it appears that a precondition for high coverage is adequate (sufficient) supply of drugs. For instance, the only village with high coverage in Yola received the highest number of ivermectin tablets (4300). The qualitative data reveals that this village is one of the few ones where the number of tablets received was perceived to be "enough to go round many people".

It is important to note that 24 of the 37 villages in the high coverage category have community designed distribution systems. The community designed programme has certain features which are particularly observable in communities with high coverage levels. One of such features is the flexibility of the distribution mode. Decisions on how and where (in case of a central mode of distribution) were based on the convenience of the people (not the distributors) and the need to reach everybody. Where an initial mode of distribution was found not to achieve these two objectives, especially that of reaching everybody, the method was immediately changed.

In two of the villages in the Enugu site and one village in the Uganda site, for instance, the initial mode of distribution was central. However, the distributors were conscientious enough to change the mode of distribution to house to house when it was discovered that not many people came to the central locations to receive the drugs. The change in distribution mode was found to lead to a higher coverage in both villages. Similarly, in one of the villages in the Yaba site, not only was the mode of distribution changed but the distributor also was changed. In a Focus group discussion with females in the village, it was reported that:

"we first used a central point, but because people didn't come out, it was decided to go from house to house..the village head distributed the first time but the second time, he appointed Dauda.."

Also in Ghana, the change in the distribution system did not affect only the place of distribution, it also affected the time of distribution. In a focus group discussion in one of the high coverage villages, it was revealed that:

"The initial distribution was done in the school where all of us collected the tablets. This time, the community decided to collect the tablets from the distributor's house at their own free time, usually early in the morning. The tablets are taken in the presence of the distributors... This system is ideal for us because it allows us to collect the tablets at our own time.." "

Another feature of the community designed programme that appears to be associated with high coverage is the freedom of the community to select the distributors. In fact, it was observed that in some of the PD villages with high coverage levels, the community leaders/elders had some input in the selection of the distributors. The communities anchored their choice of the distributors on certain characteristics: trustworthiness, respectability, competence and literacy. In addition, all the distributors are indigenes of the communities and reside in them. By being indigenes of the communities, most of the distributors perceived their benefits in terms of the success of the programme in their villages.

7.2. Treatment coverage and characteristics of the distribution system

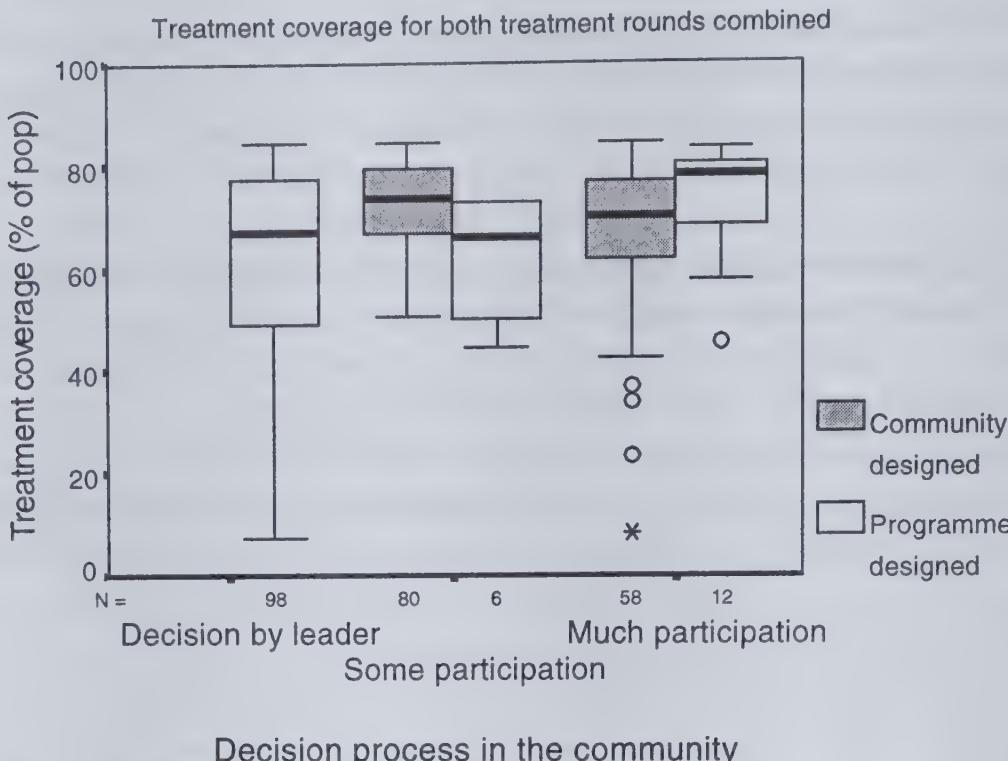
Using the quantitative data from the household survey, the relationship between treatment coverage and the main characteristics of the distribution system was analysed. The following characteristics were taken into account: (I) the decision process at the community level, (ii) the distribution process (mode of distribution, number of distributors, involvement of women and cost sharing), (iii) characteristics of the distributors and (iv) supervision. For this analysis the treatment coverage for both treatment rounds combined was used as this index was believed to be more sensitive to variation of the performance of the distribution system and less affected by the external problems of drug supply to the district.

This section describes the relationship between treatment coverage and each of the above factors separately. The subsequent section will provide the results of a multivariate regression analysis of treatment coverage on all factors together. For the analysis in this section we have used box-and-stem plots to describe the distribution of treatment coverage for each of the categories of the variable concerned, and with a breakdown by study design, i.e. community-designed (CD) or programme-designed (PD). A guideline for the interpretation of box plots is given in chapter 2.3. The Kruskal-Wallis test has been used to test for each study design the significance of the relationship between treatment coverage and the variable in question.

7.2.1 DECISION PROCESS

In the CD villages there was always participation of the community in the decision process. As the graph below illustrates, there was no significant difference in coverage in CD villages according to the extent of participation. In most of the PD villages the main decisions were taken by the village leaders.

Treatment coverage by decision process



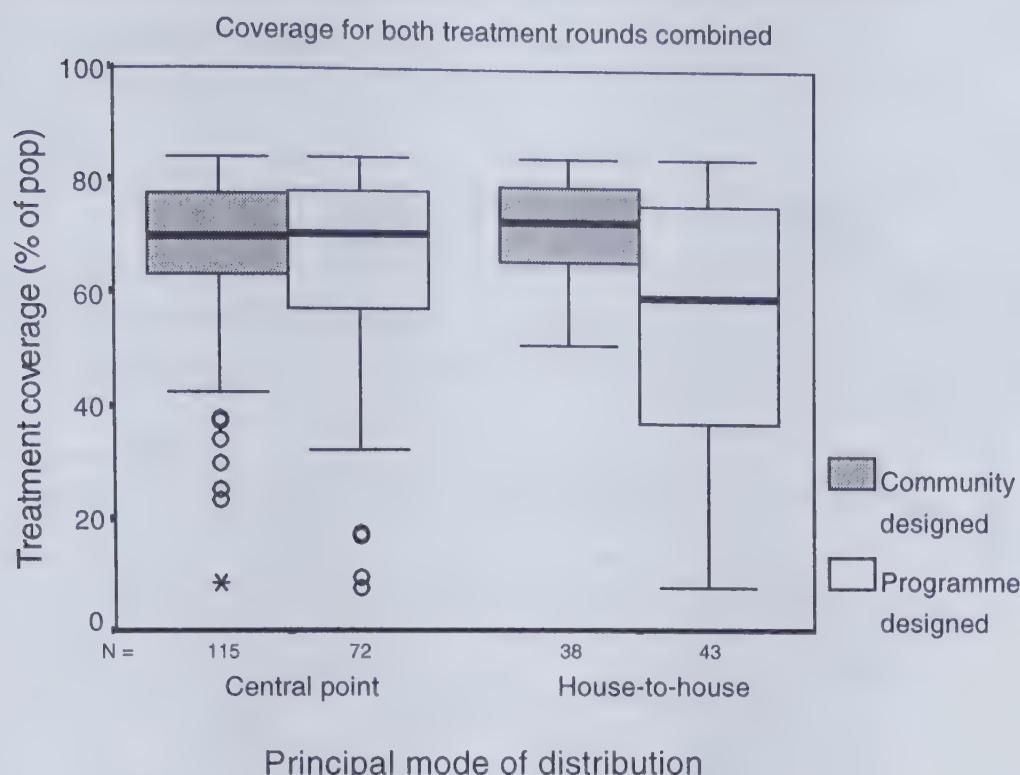
However, there were still 12 villages where there was much participation of the community in the process, and in these villages the coverage was higher ($P=0.025$).

7.2.2 DISTRIBUTION PROCESS

a Mode of distribution

The most common mode of distribution was distribution at a central point in the community. House-to-house distribution was undertaken in some 80 communities, with about equal numbers in the CD and PD group. Among the CD communities, there was no difference in coverage between central point and house-to-house distribution. Among the PD villages, however, the treatment coverage was significantly lower in communities where house-to-house distribution was used ($P=0.02$). However, this is a statistical artifact due to the confounding effect of the low coverage in Yola. Of the 43 PD communities with house-to-house distribution, as many as 18 are from Yola where the treatment coverage was low because of drug shortage and irrespective of the mode of distribution. After exclusion of all Yola communities from the analysis, there is also no difference in treatment coverage between central point and house-to-house distribution among PD villages.

Treatment coverage by mode of distribution

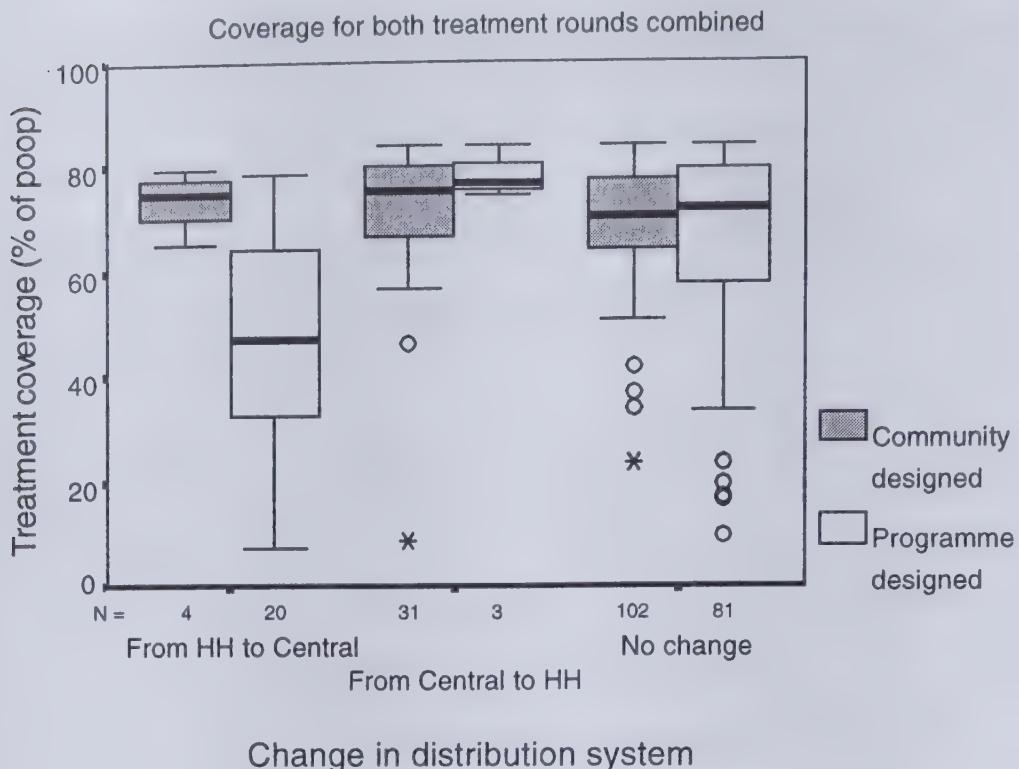


b Change in Mode of Distribution

There were two types of changes in the mode of distribution between the first and the second round of treatment. The first was a change from the central point distribution mode to house-to-house distribution. This occurred in 34 villages, nearly all of which were community-designed. The treatment coverage among the 31 CD villages which changed from central to house-to-house distribution was higher than among those which did not change, but the difference was not statistically significant. However, this finding is of interest as these type of changes occurred in all study sites and the decision to change was usually taken after careful consideration by the distributors and the community. Furthermore, in the multivariate regression analysis the change from central point to house-to-house distribution was significantly correlated with higher treatment coverage (see 7.3).

The second change was from house-to-house to central point distribution. This change was observed in 24 villages. Of those, 20 of were programme-designed and the treatment coverage in these PD villages was significantly lower than in the other PD villages ($P<0.001$). However, no less than 14 of these villages were from Yola where the programme design was that distribution had to be undertaken house-to-house by village heads or women distributors. The house-to-house distribution by village heads was not considered appropriate in many communities and hence the large number of changes in Yola to central point distribution (see 4.2.1). Among the PD villages in Yola, there is no significant difference between those which villages which changed the distribution system and those which did not. Thus, the apparent reduction in coverage in PD villages which changed from house-to-house to central distribution, as shown in the figure below, is the result of the confounding effect of low coverage in Yola.

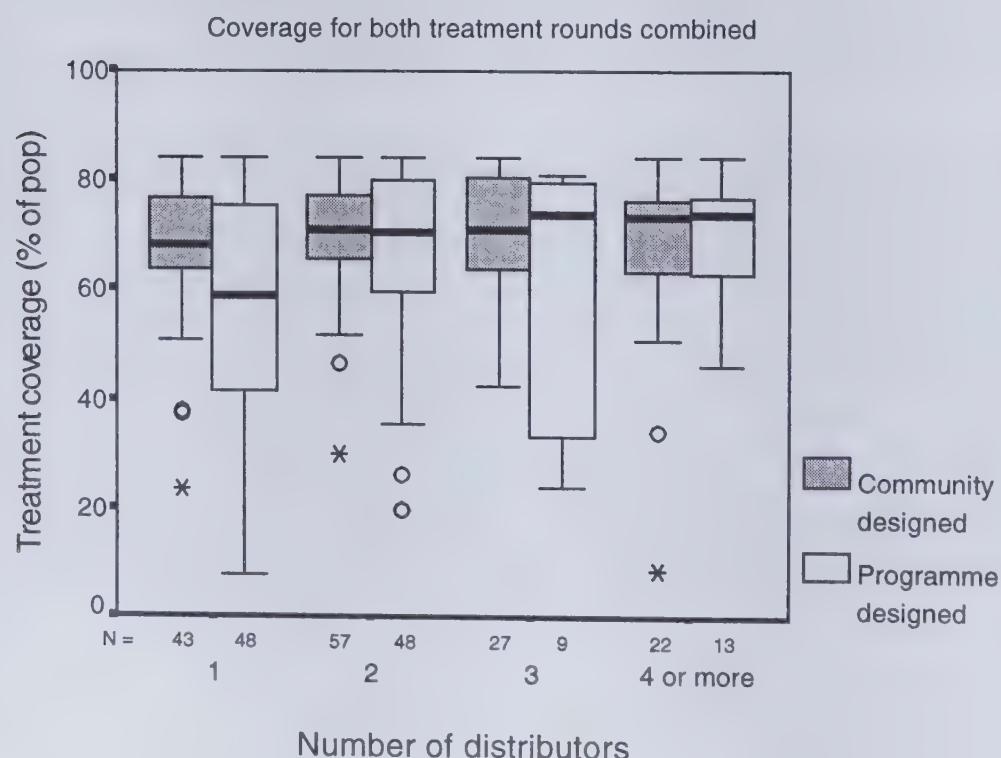
Coverage and change in distribution mode



c Number of distributors

Among CD villages, there appears to be little relationship between coverage and the number of distributors. Among PD villages, the coverage is significantly less among villages with one distributor only ($P=0.033$). Of the 48 PD villages with one distributor, 35 are from Yola and Cameroon. These are the sites with the lowest coverage overall, and this could be a confounding factor. However, if Yola

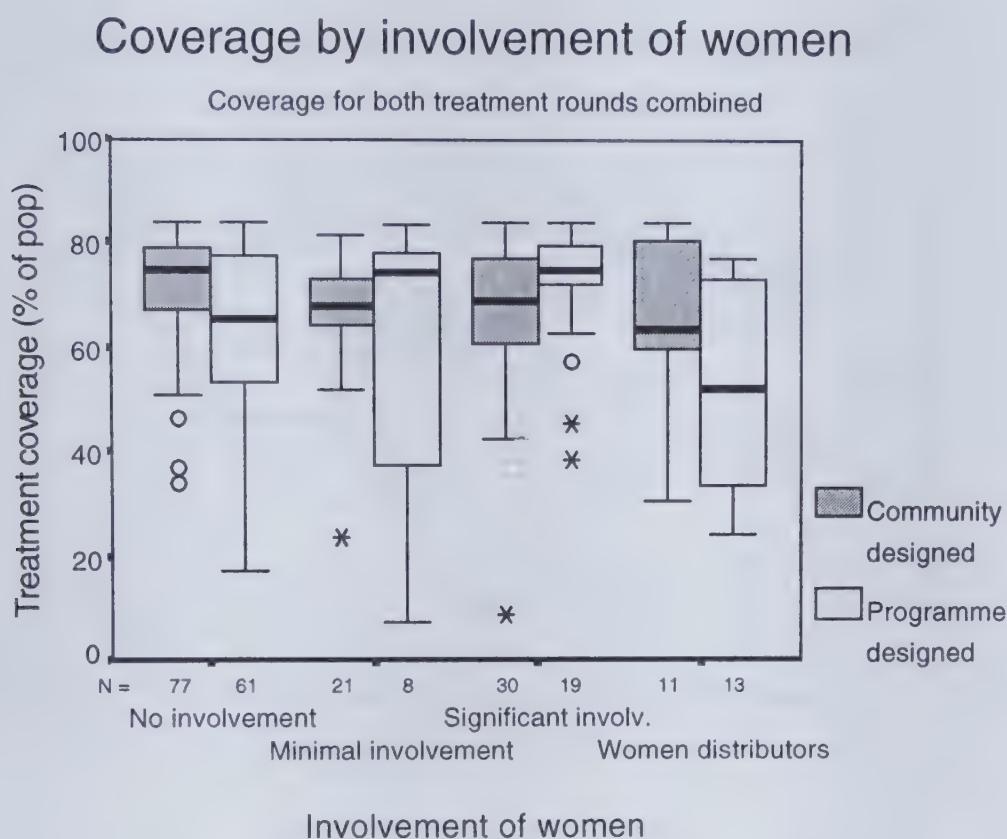
Coverage by number of distributors



and Cameroon are removed from the analysis, there remain 13 PD villages with one distributor, and these villages had much lower coverage than the other PD villages, even though with this small number the difference is no longer statistically significant. These results would suggest, however, that one single distributor per village may not be adequate.

d Involvement of women

There was no clear relationship between treatment coverage and the involvement of women in the distribution process. Only in villages where the distributors themselves were women, was the coverage significantly lower compared to the other villages ($P=0.002$ among CD villages; $P=0.001$ among PD



villages). This result, however, can also be attributed to a confounder. Of the 24 villages with women distributors, 16 were from the sites with the lowest overall coverage, i.e. 7 were from Yola and 9 from Cameroon (where the distributors were female nurses). Among the other sites, there was no difference in coverage between villages with male or female distributors.

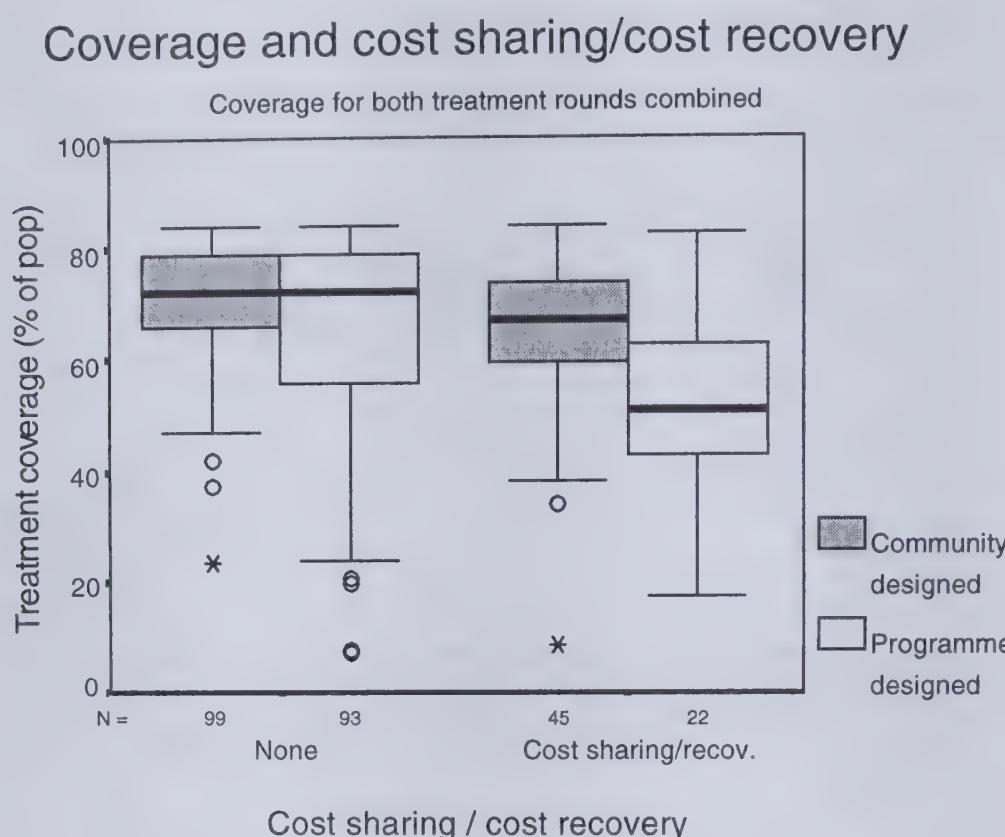
e Cost recovery/ cost sharing

Communities were also classified according to the presence or absence of a cost sharing/cost recovery mechanism. As the following figure shows, the coverage was much lower among villages with cost sharing or cost recovery, and the difference with communities where there were no such mechanisms is statistically significant for both CD and PD ($P=0.002$ for CD and $P=0.001$ for PD).

A more detailed analysis of the data revealed that the difference is largely due to the results for Cameroon which is the only country in the study where there is an official cost recovery system. For

each ivermectin treatment, an amount of CFA 100 is charged for the service cost and the treatment card. This cost recovery system was included in the study in about half of the villages, both in CD and in PD. In the other half of the villages, there was for the purpose of the study no cost recovery. Among the Cameroon communities with cost recovery, the median coverage was only 54.8% compared to 72.7% among communities without cost recovery. The difference was most pronounced and statistically significant among PD villages ($P=0.003$).

After removal of Cameroon from the analysis, the difference in coverage between communities with and without cost sharing/recovery was less pronounced (65.9% versus 72.1%) and only of borderline significance ($P=0.06$ in CD and $P=0.05$ in PD).



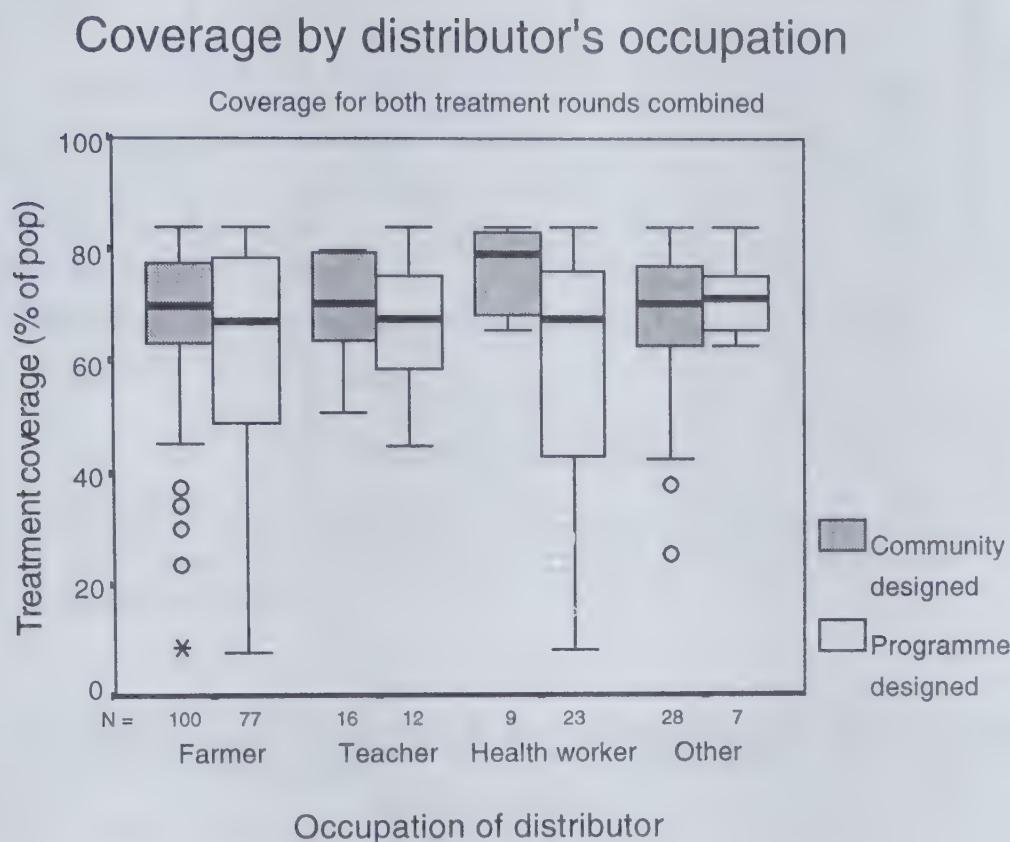
7.2.3 CHARACTERISTICS OF THE DISTRIBUTORS

a Gender and literacy

As shown in chapter 4, nearly all distributors were males. Only in Yola and Cameroon were female distributors frequent; in Yola by design and in Cameroon by selection of nurses as distributors, many of whom were females. The coverage among this group has been discussed above. Illiterate distributors were even less frequent than female distributors and their number was too small to allow a meaningful analysis of the relationship with treatment coverage.

b Occupation

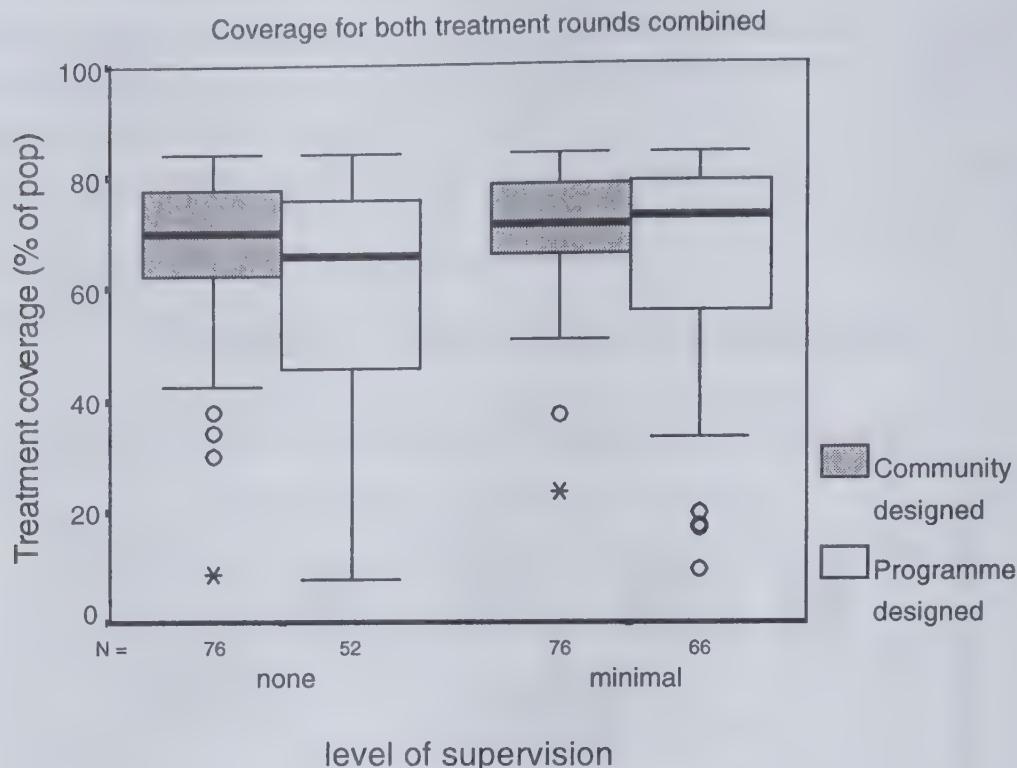
The treatment coverage was similar for all occupation categories of the distributors. The only exception was the higher coverage in the 9 community design villages where the selected distributor was a health worker ($P=0.02$). These distributors were active PHC workers or retired health workers. They were all indigenous or residents of the village, and they were all individuals in whom the community expressed great confidence.



7.2.4 SUPERVISION

When analysed by level of supervision, there was no difference in treatment coverage for both treatment rounds combined among the community design villages. Among the programme design villages the coverage was slightly higher among those with minimal supervision compared to those without supervision, but the difference was not statistically significant. However, for the treatment coverage during the second round, the difference among the programme designed villages was much more pronounced with a median of 31% coverage when there was no supervision compared to a median of 50% when there was limited supervision ($P=0.005$). Among the community designed villages the difference in coverage during the second round by level of supervision was much smaller (57% versus 61%) and not significant.

Treatment coverage by supervision



7.3. Multivariate analysis of factors related to treatment coverage

As was pointed out in the previous chapter, there were many instances where the analysis of the relationship between treatment coverage and individual characteristics of the distribution system was complicated by interference of confounding factors. It was therefore necessary to undertake a multivariate regression analysis of treatment coverage in which all relevant characteristics could be studied together and the effect of confounding could be controlled.

A stepwise regression analysis was undertaken for both indices of treatment coverage, and the following groups of variables were included in the analysis:

- Study sites
- Study design (CD versus PD)
- Decision process (Decision leader, limited or full participation)
- Sex, literacy and number of distributors
- Cost sharing/cost recovery
- Involvement of women
- Mode of distribution (Central, House-to-house)
- Change in the distribution system
- Supervision

The results of the regression analysis are given in table 7.1 for the treatment coverage in both rounds combined and in table 7.2 for the coverage during the second round. The tables list the variables which were selected in the final regression model during the stepwise regression process.

Table 7.1: Multivariate regression analysis of treatment coverage for both treatment rounds combined^a

Variables in the final regression model	Unstandardized Coefficients		Beta	t	Sig.
	B	Std. Error			
(Constant)	79.268	4.939		16.050	.000
Yola	-16.161	2.630	-.340	-6.144	.000
Cameroon	-7.814	2.469	-.176	-3.165	.002
Cost sharing / cost recovery	-7.140	2.073	-.187	-3.444	.001
Study design (CD versus PD)	-5.537	1.736	-.168	-3.190	.002
Mali	6.913	2.529	.153	2.734	.007
Yaba	6.668	2.922	.124	2.282	.023
Supervision	3.420	1.701	.104	2.011	.045

a. Dependent Variable: treatment coverage during both treatment rounds combined

As expected, several site specific variables were selected in the final regression model, i.e. Yola and Cameroon which had each a lower than average coverage, and Mali and Yaba which had very high coverages. But there were also three general characteristics of the distribution systems in the final model.

The study design was one of them, with the community design villages having higher coverage than the programme design villages.

The second factor was cost sharing or cost recovery, with the villages with cost sharing/recovery having lower treatment coverage. As discussed in the previous chapter, this is mainly due to the cost recovery system in Cameroon. When the regression analysis was repeated without the Cameroon villages, cost sharing/recovery was no longer a significant factor and not selected in the regression model (instead, ‘much participation in the decision process’ was selected in the model).

The third factor is supervision. Treatment coverage was higher among village with some supervision compared to those without supervision, especially among the programme designed villages.

Table 7.2: Multivariate regression analysis of treatment coverage during the second round only^a

Variables in the final regression model	Unstandardized Coefficients		Standard. Coefficients Beta	t	Sig.
	B	Std. Error			
(Constant)	37.333	10.727		3.480	.001
Yola	-11.812	4.878	-.142	-2.422	.016
Uganda	23.238	5.620	.235	4.135	.000
Enugu	24.233	5.584	.257	4.340	.000
Change from Central to House-House	16.331	4.961	.189	3.292	.001
Healthworker as distributor	16.362	5.050	.184	3.240	.001
Study Design (CD versus PD)	-10.482	3.370	-.182	-3.111	.002
Cost sharing or cost recovery	-8.887	3.928	-.133	-2.263	.024
House-House distribution	7.669	3.849	.119	1.993	.047

a. Dependent Variable: treatment coverage during second round

The regression model for treatment coverage during the second round (table 7.2), shows also several site variables: again Yola with a lower than average coverage because of drug shortage, and Uganda and Enugu with the highest coverage. In addition, the model includes five general characteristics of the distribution system.

The study design was again selected, with higher treatment coverage for community design compared to programme design. Cost sharing/recovery featured also in this model, and the explanation is similar to that given above for both treatment rounds combined.

New in this model, however, are the selection of a variable for 'change from central distribution to house-to-house distribution' and for 'house-to-house distribution'. As shown in the previous chapter, this change occurred nearly exclusively in CD villages. It is interesting to note that the 'change' variable is more important in the model than the house-to-house distribution itself. A possible explanation may be that house-to-house distribution is potentially more effective, but as it also involves more work, only if the community and the distributor in particular, support this mode of distribution. The decision to change from central to house-to-house distribution was often taken by the distributors, thus indicating their commitment to this distribution mode in the villages concerned. The selection of the change variable underscores the importance of building flexibility into the Community Directed treatment system, and allowing communities to make changes in their distribution system when they themselves consider this necessary.

The last variable is the health worker as distributor, with higher treatment coverages in the villages where the distributor was a health worker. These were mainly CD villages where the community selected an individual health worker in whom they had confidence.

7.4. Concluding remarks

A regular and reliable supply of ivermectin at the district level is critical for the success of the distribution programme. In the present study, the most serious failures in the distribution system were directly related to inadequate supply of the drug. However, where adequate supplies were available at the district level, communities were very capable to collect the drug themselves for treatment of their own community.

The degree of freedom of the community members to design their own treatment system, to select the type of distributors they want and to change the systems when necessary are important factors that influence the success of the programme. Community Directed Treatment systems which were designed by communities themselves did not appear to be greatly different from those designed for them by control programmes in terms of the type of distributors and the mode of distribution. However, the study shows consistently that community designed systems were more effective and achieved better treatment coverage. The study highlights the need to have distributors who are based in the communities and are trusted by their community members. Distributors who reside outside of the villages are less likely to reach the people. Resident distributors tend to better appreciate the local competing priorities of the communities and hence adjust distribution modes and times to accommodate these priorities.

Some basic supervision by the local health services was associated with better performance in terms of treatment coverage than no supervision at all. The inclusion of cost recovery, as in Cameroon, had a negative effect on treatment coverage.



8. Reporting

One of the objectives of the study was to evaluate the ability of CDDs to report on the ivermectin treatment in their community. In this chapter we will focus on the evaluation of the reported treatment coverage as calculated from the reported number of persons treated and the reported census population per village. The reasons for this choice are two-fold: the reported treatment coverage is one of the most important indices for routine monitoring of large scale ivermectin treatment, and secondly, in the present study it can be validated by comparing the reported coverage which the coverage estimated from the independent results for the household survey.

In the villages with a community designed distribution system, the mode of the record keeping was to be decided upon by the community, while in the villages with a programme designed system, use was to be made of either a notebook or the simplified pictorial forms. Nearly all villages in PD and CD opted for the note book as the means of recording the required information.

"I kept information of people treated, refusals, sick, pregnant and lactating mothers less than one week in a notebook." (INDEPTH, DISTRIBUTOR, KADUNA.)

"I write names in books to remember those treated; checks in the register to treat others later." (IDP, UGANDA)

"I use my census results and records in my register to tell the quantity. Also my register will show the number of treated persons and the number yet to take." (INDEPTH, CD, ENUGU.)

Pictorial reporting forms originally designed for illiterate distributors were used only in Yola and Mali. In Yola the pictorial forms were also used as a health education material during initial contacts with the villages and subsequent health education campaign.

"We have written all our work result and needs in the paper provided and have given them to the village head to send back to Takum." (IDP, YOLA.)

8.1. Reported treatment coverage

Communities were required to report for each round of treatment, the dates of first and last treatment, total population, total number of people treated, number with severe adverse reaction, number of tablets received, number of tablets distributed, number of tablets kept for absentees, pregnant women and sick people, number of tablets to be returned and number of tablets required for the next distribution exercise. This information was reported on the so-called village summary forms except in Yola and Mali where pictorial forms were used for this purpose.

Distributors complained of problems in compiling these reports:

"We used the treatment reporting form but the mathematical calculations worry me. Sometimes adding half dosages worry me" (INDEPTH, DISTRIBUTOR, GHANA.)

Of the 272 villages with a final evaluation, summary record forms for the second round of treatment could be linked with the main data base for the household survey for only 143 villages. The inability to link the two records in the other villages was mostly due to lack of treatment summary forms from Cameroon and Yola, for which the processing of the information on the treatment summary forms was yet to be completed at the time of analysis, and from villages in other study sites where no second round treatments had yet been given at the time of the evaluation. Finally, there were 12 villages for which there were discrepancies between the village name as recorded by the CDD on the village summary forms and the name on the household survey forms, and these villages were therefore excluded from the present analysis.

For the 143 villages, the average treatment coverage during the second round was 65% according to the summary reports but only 54.4% according to the results of the household survey (Table 8.1).

Table 8.1: Treatment coverage as reported and as estimated in survey by study site

SITE		N	Mean percent coverage	Std. Dev.	Median percent coverage	Minim-um	Maxi-mum
Ghana	Reported	36	55.3	17.3	56.0	25.0	100.0
	Survey	36	37.3	28.3	31.9	.0	84.0
Kaduna	Reported	26	66.4	17.8	66.5	14.0	100.0
	Survey	26	45.7	24.4	52.8	.0	84.0
Yaba	Reported	8	85.3	11.0	86.0	69.0	100.0
	Survey	8	68.7	28.3	79.9	.0	84.0
Enugu	Reported	27	65.9	13.8	64.0	45.0	97.0
	Survey	27	61.6	11.7	62.0	42.0	84.0
Mali	Reported	26	63.3	16.1	65.0	38.0	92.0
	Survey	26	67.3	15.9	70.9	.8	84.0
Uganda	Reported	20	74.0	15.3	73.0	47.0	96.0
	Survey	20	64.4	9.1	63.6	43.8	82.4
Total	Reported	143	65.0	17.5	65.0	14.0	100.0
	Survey	143	54.4	24.0	61.1	.0	84.0

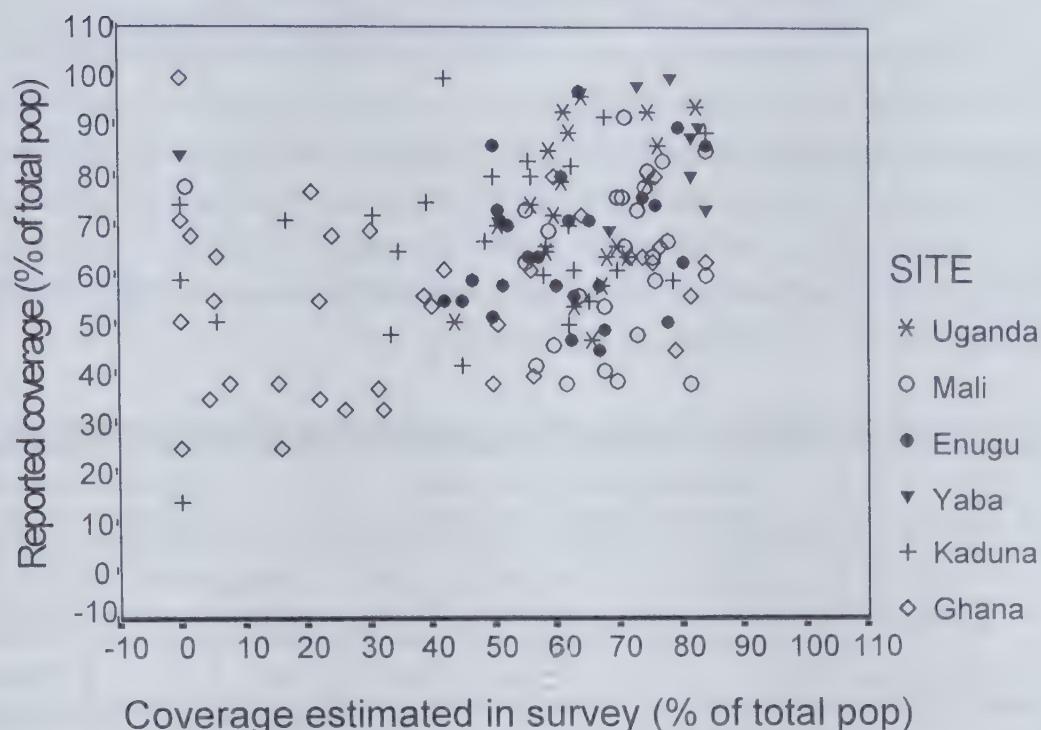
The type of differences between reported and estimated treatment coverage per village are shown in Figure 8.1. For villages for which the estimated treatment coverage is very low, the reported coverage is always much higher. There are even several villages for which the estimated coverage was equal to zero and the reported coverage more than 50%. With such extreme differences, one might suspect that some of the reports are for the different rounds of treatment. However, this is unlikely as the treatment dates recorded on all 143 summary forms were those of the second treatment round.

For the villages with an estimated coverage of more than 50%, the difference between reported and estimated coverage is less extreme, taking also into account that the survey estimate is based on a sample of about 75 interviewees per village and thus subject to random variation. Nevertheless, even in this group of villages, the reported coverage is higher than the estimated coverage. For instance, in Uganda where there were no villages with a low coverage, the average reported treatment coverage of

74% is still 10% higher than the estimated coverage. Only for Mali and Enugu is there little difference between reported and estimated coverage.

Fig. 8.1: Reported versus estimated coverage

Results for second treatment round



Possible explanations for the over-reporting of treatment coverage may be a tendency to report for eligibles only, under-reporting of the census population, or both.

Table 8.2: Treatment coverage as reported and as estimated in survey by design

Design		N	Mean percent coverage	Std. Dev.	Median percent coverage	Minim-um	Maxi-mum
Community designed	Reported	93	63.7	18.2	64.0	25.0	100.0
	Survey	93	56.7	23.1	62.7	.0	84.0
Programme designed	Reported	50	67.6	16.1	68.5	14.0	100.0
	Survey	50	50.1	25.3	54.0	.0	84.0
Total	Reported	143	65.0	17.5	65.0	14.0	100.0
	Survey	143	54.4	24.0	61.1	.0	84.0

Table 8.2 shows the results by study design. The difference between reported and estimated coverage is much greater among the programme design villages than among the community design villages. This is somewhat of a surprise given that the programme design villages used the standard reporting format of the control programmes and that they underwent the standard training in its use.

8.2. Reported adverse reactions

CDDs were also required to note in the summary report the total number of persons who after treatment experienced (i) severe dizziness or inability to walk and (ii) difficulty in breathing. The results are given in table 8.3 by site. Cases with severe dizziness/inability to walk were reported from 27% of the villages, and in two sites from up to 60% of the villages. Difficulty with breathing was reported for 14% of the villages. The number of reported cases per village varies considerably with one village in Kaduna reporting 40 cases of severe dizziness and one village in Mali reporting 38 cases with difficulty in breathing. As the summary reports contain only total numbers, it was not possible to trace the individuals concerned and validate the information. However, compared to the few adverse reactions which were referred to the nearest health facility according to the qualitative data (chapter 5.3), the reported number of severe adverse reactions seems extremely high. It is likely that the reported number is an overestimation resulting from differences in the interpretation of what constitutes 'severe dizziness' or 'difficulty in breathing'.

Table 8.3: Summary of reports of severe adverse reactions by study site

Study site	Number of villages	Reported cases with severe dizziness / inability to walk				Reported cases with difficulty in breathing			
		Villages with reported cases		No. of cases per reporting village		Villages with reported cases		No. of cases per reporting village	
		No.	%	Mean	Max.	No.	%	Mean	Max.
Ghana	36	4	11.1	2.5	3	1	2.8	1	1
Kaduna	26	5	19.2	15.4	40	3	11.5	4.3	10
Yaba	8	0	0.0	-	-	0	0.0	-	-
Enugu	27	3	11.1	9.7	18	2	7.4	5.5	10
Mali	26	15	57.7	5.3	15	9	34.6	9.4	38
Uganda	20	12	60.0	5.6	12	5	25.0	2.4	5
Total	143	39	27.3	6.7	40	20	14.0	6.1	38

8.3. Concluding remarks

The results in this chapter indicate that the reliability of the reported information on treatment coverage leaves much to be desired, and that the actual treatment coverage may be much lower than that routinely reported. The fact that the discrepancies were greatest among the programme design villages suggests that the solution to this problem may not be merely a matter of more training in the use of the current reporting tools. Instead, it may be necessary to reconsider the whole approach to reporting, to redefine the absolute minimum information required and for what purpose, and to investigate if there are no alternative and more reliable ways of collecting this minimum information. For example, of the six sites included in this analysis, the pictorial reporting form was used only in Mali and this was the site with the least difference between reported and estimated treatment coverage. Further studies on the pictorial form and alternative reporting mechanisms, seem therefore warranted. The reports on severe adverse reactions also indicate the need for a reconsideration of the reporting system as the information provided in the current reports does not appear very meaningful.

9. Sustainability and Replicability

9.1. Sustainability indicators

Although experience from various community development programmes suggests several indicators that may predict the sustainability of various health programmes, validating these indicators requires study of outcomes of practical significance over time. Experience of the researchers implementing Community Directed Treatment programmes in this study suggests the following indicators may be suitable:

- Community involvement in designing distribution systems and selecting distributors
- Flexibility to change the distribution system, as indicated by local experience
- Availability of ivermectin from central source
- Availability of credible distributors
- Leadership to facilitate effective functioning of the distribution system
- Integration with local health system
- Social and political stability of community
- Perceived benefits of ivermectin
- Availability of local resources to maintain the system

9.1.1 COMMUNITY INVOLVEMENT IN DESIGNING DISTRIBUTION SYSTEM AND SELECTING DISTRIBUTORS

In several communities, the distribution system was designed by members of the communities or their representatives. The study demonstrates that communities have tended to design systems that are convenient for them. Even where the distribution system was initiated from outside, the communities participated in the selection of the distributors. The distributors were found to be individuals who were trusted and respected.

9.1.2 FLEXIBILITY TO CHANGE THE DISTRIBUTION SYSTEM, AS INDICATED BY LOCAL EXPERIENCE

The study found that flexibility to change the distribution system was a feature of those villages with better coverage. Several communities changed their initial mode of distribution when found to be inconvenient or inadequate to alternatives that worked better for them. In addition, there were also reports from some communities that they had particular preferences concerning seasonality and the time of distribution, to ensure minimal disruption of economic activities, especially farming. Some communities collected ivermectin from the central source at the time specified by the research team, but because of concern about side effects that might affect their productivity, they delayed distribution until a time when any side effects would have the least adverse impact (eg, after the harvest).

9.1.3 AVAILABILITY OF IVERMECTIN FROM THE CENTRAL SOURCE

An important element of the programme is the availability of ivermectin at the central store. The structures that are put in place for the distribution of the drug locally can be effective only when there are drugs to distribute. The study reveals that low coverage in some communities (particularly in Yola site) is due to unavailability of drugs. The study also reveals the frustration of some distributors or leaders who could not get ivermectin on time in some communities.

9.1.4 AVAILABILITY OF CREDIBLE DISTRIBUTORS

The choice of distributors was the responsibility of the communities for the community designed distribution systems. Even in the programme designed systems when communities were given guidelines for the selection (eg, to include females), the actual selection of the distributors was done by the community. Criteria on which this selection was made included honesty, being indigenous to the community, respectability, experience with similar tasks in the past, and literacy. By selecting individuals who are perceived to be credible, the communities were able to identify with the programme. In some cases, bad character and criminal behaviour impaired operations of the distribution. In some cases, the willingness of other people to serve as substitute distributors when the designated distributors were unavailable enhanced the effectiveness of the system.

9.1.5 LEADERSHIP TO FACILITATE EFFECTIVE FUNCTIONING OF THE DISTRIBUTION SYSTEM

Even though the style of leadership varied, good leadership was an important determinant of successful distribution. Communities relied on their leaders to take important decisions on their behalf. Leadership was necessary to motivate people to participate in the programme and to follow up when necessary to ensure their communities received ivermectin.

9.1.6 INTEGRATION WITH LOCAL HEALTH SYSTEM

Many of the communities where ivermectin is to be distributed already have a functioning health system and various health and development programmes. In Mali, for instance, the programme-

designed system operated with the ongoing activities of an NGO. In other settings, health officials contributed to health educational activities. Local government or district-level offices assisted in the distribution to the communities in different ways. Although it may not always be possible or desirable to fully integrate activities with the existing programmes, it is nevertheless desirable to avoid competition and conflict.

9.1.7 PERCEIVED BENEFITS OF IVERMECTIN

Most villagers participating in the study were eager to take ivermectin and considered it a helpful drug. Even when side effects were acknowledged, these typically affected the timing rather than the desire to take the drug.

9.1.8 AVAILABILITY OF LOCAL RESOURCES TO MAINTAIN THE SYSTEM

Although there are some requirements for local resources, for the most part they are minimal. Sticks for measuring height are readily available locally. When it did not interfere with the work, people were willing to give the time needed to receive the drug. Some distributors indicated their desire for compensation; although the willingness of the community to support them in various ways may contribute to the sustainability of programmes, introducing a payment system must be weighed against the potential for corruption.

9.1.9 SOCIAL AND POLITICAL STABILITY OF COMMUNITY

In the absence of political stability it is impossible for any programme with complex links between communities, districts, and international organizations to function effectively. Experience in this study also showed instances where disruptions in the social system (eg, deaths in the family of local leaders) seriously impaired distribution.

Many of these factors were associated with the effective implementation of the current distribution programmes. It is anticipated they are also likely to be determinants of sustainability and should be considered in current planning for Community Directed Treatment with ivermectin and comparable health programmes. To validate this hypothesis, however, it would be useful to rate villages with reference to these parameters and evaluate the effectiveness of their distribution systems over time.



10. Conclusions and Recommendations

10.1. Main conclusions

- Community Directed Treatment with ivermectin is feasible and effective.
- Community Directed Treatment has been successful in a wide range of geographic and cultural settings in Africa and therefore is likely to be replicable in other endemic communities in Africa.
- Although sustainability can only be proven over time, the current study indicates Community Directed Treatment is likely to be sustainable, as reflected by:
 - the commitment of community leaders and distributors;
 - the high degree of involvement of the communities and their willingness to commit available local resources to the distribution process;
 - the ability of communities to collect ivermectin at the appropriate time from district level stores;
 - the perceived benefits of ivermectin and the high demand for it in communities where onchocerciasis is endemic;
 - the ability of the communities to recognise the problems with distribution methods and modify the methods accordingly.
- Distribution systems designed by the communities themselves achieved better coverages than distribution systems designed for them by control programmes. Since community-designed systems provided more opportunities for community involvement, they appear to have greater potential for sustainability.
- The performance of the distributors appears adequate, as shown by the coverages achieved and the apparent adherence to exclusion criteria and use of appropriate dosing.
- Non-availability and inadequate quantity of ivermectin impaired coverage in several study sites.
- The provision of some basic supervision by the local health services was associated with better performance of the distribution systems in terms of treatment coverage. Cost recovery had a negative effect on treatment coverage.
- Communities had difficulties in preparing reports as requested.

10.2. Recommendations

- Community Directed Treatment with ivermectin should become a principal method for onchocerciasis control in Africa.
- In view of enhanced potential for sustainability, preference should be given to community-designed approaches.
- Special provisions and arrangements are required to ensure adequate availability and accessibility of ivermectin from district-level sources.
- In view of problems with record keeping at the community level, there is an urgent need to reassess both current information requirements and ways of collecting the required information.
- Follow-up research is required to validate indicators of sustainability identified in this study and to identify appropriate modifications of Community Directed Treatment based on additional experience.

